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(Original Signature of Member)

111TH CONGRESS
1ST SESSION

H. R. _____

To protect the public health by providing the Food and Drug Administration
with certain authority to regulate tobacco products.

IN THE HOUSE OF REPRESENTATIVES

Mr. WAXMAN introduced the following bill; which was referred to the
Committee on _____

A BILL

To protect the public health by providing the Food and
Drug Administration with certain authority to regulate
tobacco products.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Family Smoking Prevention and Tobacco Control Act”.

6 (b) TABLE OF CONTENTS.—The table of contents of
7 this Act is as follows:

Sec. 1. Short title; table of contents.

Sec. 2. Findings.

- Sec. 3. Purpose.
- Sec. 4. Scope and effect.
- Sec. 5. Severability.

TITLE I—AUTHORITY OF THE FOOD AND DRUG ADMINISTRATION

- Sec. 101. Amendment of Federal Food, Drug, and Cosmetic Act.
- Sec. 102. Final rule.
- Sec. 103. Conforming and other amendments to general provisions.
- Sec. 104. Study on raising the minimum age to purchase tobacco products.
- Sec. 105. Enforcement action plan for advertising and promotion restrictions.

TITLE II—TOBACCO PRODUCT WARNINGS; CONSTITUENT AND SMOKE CONSTITUENT DISCLOSURE

- Sec. 201. Cigarette label and advertising warnings.
- Sec. 202. Authority to revise cigarette warning label statements.
- Sec. 203. State regulation of cigarette advertising and promotion.
- Sec. 204. Smokeless tobacco labels and advertising warnings.
- Sec. 205. Authority to revise smokeless tobacco product warning label statements.
- Sec. 206. Tar, nicotine, and other smoke constituent disclosure to the public.

TITLE III—PREVENTION OF ILLICIT TRADE IN TOBACCO PRODUCTS

- Sec. 301. Labeling, recordkeeping, records inspection.
- Sec. 302. Study and report.

TITLE IV—THRIFT SAVINGS PLAN ENHANCEMENT

- Sec. 401. Short title.
- Sec. 402. Automatic enrollments.
- Sec. 403. Qualified Roth contribution program.
- Sec. 404. Authority to establish self-directed investment window.
- Sec. 405. Reporting requirements.
- Sec. 406. Acknowledgement of risk.
- Sec. 407. Credit for unused sick leave.

1 **SEC. 2. FINDINGS.**

2 The Congress finds the following:

3 (1) The use of tobacco products by the Nation's
4 children is a pediatric disease of considerable pro-
5 portions that results in new generations of tobacco-
6 dependent children and adults.

7 (2) A consensus exists within the scientific and
8 medical communities that tobacco products are in-

1 herently dangerous and cause cancer, heart disease,
2 and other serious adverse health effects.

3 (3) Nicotine is an addictive drug.

4 (4) Virtually all new users of tobacco products
5 are under the minimum legal age to purchase such
6 products.

7 (5) Tobacco advertising and marketing con-
8 tribute significantly to the use of nicotine-containing
9 tobacco products by adolescents.

10 (6) Because past efforts to restrict advertising
11 and marketing of tobacco products have failed ade-
12 quately to curb tobacco use by adolescents, com-
13 prehensive restrictions on the sale, promotion, and
14 distribution of such products are needed.

15 (7) Federal and State governments have lacked
16 the legal and regulatory authority and resources
17 they need to address comprehensively the public
18 health and societal problems caused by the use of to-
19 bacco products.

20 (8) Federal and State public health officials,
21 the public health community, and the public at large
22 recognize that the tobacco industry should be subject
23 to ongoing oversight.

24 (9) Under article I, section 8 of the Constitu-
25 tion, the Congress is vested with the responsibility

1 for regulating interstate commerce and commerce
2 with Indian tribes.

3 (10) The sale, distribution, marketing, adver-
4 tising, and use of tobacco products are activities in
5 and substantially affecting interstate commerce be-
6 cause they are sold, marketed, advertised, and dis-
7 tributed in interstate commerce on a nationwide
8 basis, and have a substantial effect on the Nation's
9 economy.

10 (11) The sale, distribution, marketing, adver-
11 tising, and use of such products substantially affect
12 interstate commerce through the health care and
13 other costs attributable to the use of tobacco prod-
14 ucts.

15 (12) It is in the public interest for Congress to
16 enact legislation that provides the Food and Drug
17 Administration with the authority to regulate to-
18 bacco products and the advertising and promotion of
19 such products. The benefits to the American people
20 from enacting such legislation would be significant
21 in human and economic terms.

22 (13) Tobacco use is the foremost preventable
23 cause of premature death in America. It causes over
24 400,000 deaths in the United States each year, and

1 approximately 8,600,000 Americans have chronic ill-
2 nesses related to smoking.

3 (14) Reducing the use of tobacco by minors by
4 50 percent would prevent well over 10,000,000 of to-
5 day's children from becoming regular, daily smokers,
6 saving over 3,000,000 of them from premature
7 death due to tobacco-induced disease. Such a reduc-
8 tion in youth smoking would also result in approxi-
9 mately \$75,000,000,000 in savings attributable to
10 reduced health care costs.

11 (15) Advertising, marketing, and promotion of
12 tobacco products have been especially directed to at-
13 tract young persons to use tobacco products, and
14 these efforts have resulted in increased use of such
15 products by youth. Past efforts to oversee these ac-
16 tivities have not been successful in adequately pre-
17 venting such increased use.

18 (16) In 2005, the cigarette manufacturers
19 spent more than \$13,000,000,000 to attract new
20 users, retain current users, increase current con-
21 sumption, and generate favorable long-term atti-
22 tudes toward smoking and tobacco use.

23 (17) Tobacco product advertising often
24 misleadingly portrays the use of tobacco as socially
25 acceptable and healthful to minors.

1 (18) Tobacco product advertising is regularly
2 seen by persons under the age of 18, and persons
3 under the age of 18 are regularly exposed to tobacco
4 product promotional efforts.

5 (19) Through advertisements during and spon-
6 sorship of sporting events, tobacco has become
7 strongly associated with sports and has become por-
8 trayed as an integral part of sports and the healthy
9 lifestyle associated with rigorous sporting activity.

10 (20) Children are exposed to substantial and
11 unavoidable tobacco advertising that leads to favor-
12 able beliefs about tobacco use, plays a role in leading
13 young people to overestimate the prevalence of to-
14 bacco use, and increases the number of young people
15 who begin to use tobacco.

16 (21) The use of tobacco products in motion pic-
17 tures and other mass media glamorizes its use for
18 young people and encourages them to use tobacco
19 products.

20 (22) Tobacco advertising expands the size of
21 the tobacco market by increasing consumption of to-
22 bacco products including tobacco use by young peo-
23 ple.

24 (23) Children are more influenced by tobacco
25 marketing than adults: more than 80 percent of

1 youth smoke three heavily marketed brands, while
2 only 54 percent of adults, 26 and older, smoke these
3 same brands.

4 (24) Tobacco company documents indicate that
5 young people are an important and often crucial seg-
6 ment of the tobacco market. Children, who tend to
7 be more price sensitive than adults, are influenced
8 by advertising and promotion practices that result in
9 drastically reduced cigarette prices.

10 (25) Comprehensive advertising restrictions will
11 have a positive effect on the smoking rates of young
12 people.

13 (26) Restrictions on advertising are necessary
14 to prevent unrestricted tobacco advertising from un-
15 dermining legislation prohibiting access to young
16 people and providing for education about tobacco
17 use.

18 (27) International experience shows that adver-
19 tising regulations that are stringent and comprehen-
20 sive have a greater impact on overall tobacco use
21 and young people's use than weaker or less com-
22 prehensive ones.

23 (28) Text only requirements, although not as
24 stringent as a ban, will help reduce underage use of

1 tobacco products while preserving the informational
2 function of advertising.

3 (29) It is in the public interest for Congress to
4 adopt legislation to address the public health crisis
5 created by actions of the tobacco industry.

6 (30) The final regulations promulgated by the
7 Secretary of Health and Human Services in the Au-
8 gust 28, 1996, issue of the Federal Register (61
9 Fed. Reg. 44615–44618) for inclusion as part 897
10 of title 21, Code of Federal Regulations, are con-
11 sistent with the first amendment to the United
12 States Constitution and with the standards set forth
13 in the amendments made by this subtitle for the reg-
14 ulation of tobacco products by the Food and Drug
15 Administration, and the restriction on the sale and
16 distribution of, including access to and the adver-
17 tising and promotion of, tobacco products contained
18 in such regulations are substantially related to ac-
19 complishing the public health goals of this Act.

20 (31) The regulations described in paragraph
21 (30) will directly and materially advance the Federal
22 Government's substantial interest in reducing the
23 number of children and adolescents who use ciga-
24 rettes and smokeless tobacco and in preventing the
25 life-threatening health consequences associated with

1 tobacco use. An overwhelming majority of Americans
2 who use tobacco products begin using such products
3 while they are minors and become addicted to the
4 nicotine in those products before reaching the age of
5 18. Tobacco advertising and promotion play a cru-
6 cial role in the decision of these minors to begin
7 using tobacco products. Less restrictive and less
8 comprehensive approaches have not and will not be
9 effective in reducing the problems addressed by such
10 regulations. The reasonable restrictions on the ad-
11 vertising and promotion of tobacco products con-
12 tained in such regulations will lead to a significant
13 decrease in the number of minors using and becom-
14 ing addicted to those products.

15 (32) The regulations described in paragraph
16 (30) impose no more extensive restrictions on com-
17 munication by tobacco manufacturers and sellers
18 than are necessary to reduce the number of children
19 and adolescents who use cigarettes and smokeless to-
20 bacco and to prevent the life-threatening health con-
21 sequences associated with tobacco use. Such regula-
22 tions are narrowly tailored to restrict those adver-
23 tising and promotional practices which are most like-
24 ly to be seen or heard by youth and most likely to
25 entice them into tobacco use, while affording tobacco

1 manufacturers and sellers ample opportunity to con-
2vey information about their products to adult con-
3sumers.

4 (33) Tobacco dependence is a chronic disease,
5 one that typically requires repeated interventions to
6 achieve long-term or permanent abstinence.

7 (34) Because the only known safe alternative to
8 smoking is cessation, interventions should target all
9 smokers to help them quit completely.

10 (35) Tobacco products have been used to facili-
11tate and finance criminal activities both domestically
12and internationally. Illicit trade of tobacco products
13has been linked to organized crime and terrorist
14groups.

15 (36) It is essential that the Food and Drug Ad-
16ministration review products sold or distributed for
17use to reduce risks or exposures associated with to-
18bacco products and that it be empowered to review
19any advertising and labeling for such products. It is
20also essential that manufacturers, prior to marketing
21such products, be required to demonstrate that such
22products will meet a series of rigorous criteria, and
23will benefit the health of the population as a whole,
24taking into account both users of tobacco products

1 and persons who do not currently use tobacco prod-
2 ucts.

3 (37) Unless tobacco products that purport to
4 reduce the risks to the public of tobacco use actually
5 reduce such risks, those products can cause substan-
6 tial harm to the public health to the extent that the
7 individuals, who would otherwise not consume to-
8 bacco products or would consume such products less,
9 use tobacco products purporting to reduce risk.
10 Those who use products sold or distributed as modi-
11 fied risk products that do not in fact reduce risk,
12 rather than quitting or reducing their use of tobacco
13 products, have a substantially increased likelihood of
14 suffering disability and premature death. The costs
15 to society of the widespread use of products sold or
16 distributed as modified risk products that do not in
17 fact reduce risk or that increase risk include thou-
18 sands of unnecessary deaths and injuries and huge
19 costs to our health care system.

20 (38) As the National Cancer Institute has
21 found, many smokers mistakenly believe that “low
22 tar” and “light” cigarettes cause fewer health prob-
23 lems than other cigarettes. As the National Cancer
24 Institute has also found, mistaken beliefs about the
25 health consequences of smoking “low tar” and

1 “light” cigarettes can reduce the motivation to quit
2 smoking entirely and thereby lead to disease and
3 death.

4 (39) Recent studies have demonstrated that
5 there has been no reduction in risk on a population-
6 wide basis from “low tar” and “light” cigarettes,
7 and such products may actually increase the risk of
8 tobacco use.

9 (40) The dangers of products sold or distrib-
10 uted as modified risk tobacco products that do not
11 in fact reduce risk are so high that there is a com-
12 pelling governmental interest in ensuring that state-
13 ments about modified risk tobacco products are com-
14 plete, accurate, and relate to the overall disease risk
15 of the product.

16 (41) As the Federal Trade Commission has
17 found, consumers have misinterpreted advertise-
18 ments in which one product is claimed to be less
19 harmful than a comparable product, even in the
20 presence of disclosures and advisories intended to
21 provide clarification.

22 (42) Permitting manufacturers to make unsub-
23 substantiated statements concerning modified risk to-
24 bacco products, whether express or implied, even if

1 accompanied by disclaimers would be detrimental to
2 the public health.

3 (43) The only way to effectively protect the
4 public health from the dangers of unsubstantiated
5 modified risk tobacco products is to empower the
6 Food and Drug Administration to require that prod-
7 ucts that tobacco manufacturers sold or distributed
8 for risk reduction be reviewed in advance of mar-
9 keting, and to require that the evidence relied on to
10 support claims be fully verified.

11 (44) The Food and Drug Administration is a
12 regulatory agency with the scientific expertise to
13 identify harmful substances in products to which
14 consumers are exposed, to design standards to limit
15 exposure to those substances, to evaluate scientific
16 studies supporting claims about the safety of prod-
17 ucts, and to evaluate the impact of labels, labeling,
18 and advertising on consumer behavior in order to re-
19 duce the risk of harm and promote understanding of
20 the impact of the product on health. In connection
21 with its mandate to promote health and reduce the
22 risk of harm, the Food and Drug Administration
23 routinely makes decisions about whether and how
24 products may be marketed in the United States.

1 (45) The Federal Trade Commission was cre-
2 ated to protect consumers from unfair or deceptive
3 acts or practices, and to regulate unfair methods of
4 competition. Its focus is on those marketplace prac-
5 tices that deceive or mislead consumers, and those
6 that give some competitors an unfair advantage. Its
7 mission is to regulate activities in the marketplace.
8 Neither the Federal Trade Commission nor any
9 other Federal agency except the Food and Drug Ad-
10 ministration possesses the scientific expertise needed
11 to implement effectively all provisions of the Family
12 Smoking Prevention and Tobacco Control Act.

13 (46) If manufacturers state or imply in commu-
14 nications directed to consumers through the media
15 or through a label, labeling, or advertising, that a to-
16 bacco product is approved or inspected by the Food
17 and Drug Administration or complies with Food and
18 Drug Administration standards, consumers are like-
19 ly to be confused and misled. Depending upon the
20 particular language used and its context, such a
21 statement could result in consumers being misled
22 into believing that the product is endorsed by the
23 Food and Drug Administration for use or in con-
24 sumers being misled about the harmfulness of the

1 product because of such regulation, inspection, ap-
2 proval, or compliance.

3 (47) In August 2006 a United States district
4 court judge found that the major United States cig-
5 arette companies continue to target and market to
6 youth. USA v Philip Morris, USA, Inc., et al. (Civil
7 Action No. 99-2496 (GK), August 17, 2006).

8 (48) In August 2006 a United States district
9 court judge found that the major United States cig-
10 arette companies dramatically increased their adver-
11 tising and promotional spending in ways that en-
12 courage youth to start smoking subsequent to the
13 signing of the Master Settlement Agreement in
14 1998. USA v Philip Morris, USA, Inc., et al. (Civil
15 Action No. 99-2496 (GK), August 17, 2006).

16 (49) In August 2006 a United States district
17 court judge found that the major United States cig-
18 arette companies have designed their cigarettes to
19 precisely control nicotine delivery levels and provide
20 doses of nicotine sufficient to create and sustain ad-
21 diction while also concealing much of their nicotine-
22 related research. USA v Philip Morris, USA, Inc., et
23 al. (Civil Action No. 99-2496 (GK), August 17,
24 2006).

1 **SEC. 3. PURPOSE.**

2 The purposes of this Act are—

3 (1) to provide authority to the Food and Drug
4 Administration to regulate tobacco products under
5 the Federal Food, Drug, and Cosmetic Act (21
6 U.S.C. 301 et seq.), by recognizing it as the primary
7 Federal regulatory authority with respect to the
8 manufacture, marketing, and distribution of tobacco
9 products as provided for in this Act;

10 (2) to ensure that the Food and Drug Adminis-
11 tration has the authority to address issues of par-
12 ticular concern to public health officials, especially
13 the use of tobacco by young people and dependence
14 on tobacco;

15 (3) to authorize the Food and Drug Adminis-
16 tration to set national standards controlling the
17 manufacture of tobacco products and the identity,
18 public disclosure, and amount of ingredients used in
19 such products;

20 (4) to provide new and flexible enforcement au-
21 thority to ensure that there is effective oversight of
22 the tobacco industry's efforts to develop, introduce,
23 and promote less harmful tobacco products;

24 (5) to vest the Food and Drug Administration
25 with the authority to regulate the levels of tar, nico-

1 tine, and other harmful components of tobacco prod-
2 ucts;

3 (6) in order to ensure that consumers are better
4 informed, to require tobacco product manufacturers
5 to disclose research which has not previously been
6 made available, as well as research generated in the
7 future, relating to the health and dependency effects
8 or safety of tobacco products;

9 (7) to continue to permit the sale of tobacco
10 products to adults in conjunction with measures to
11 ensure that they are not sold or accessible to under-
12 age purchasers;

13 (8) to impose appropriate regulatory controls on
14 the tobacco industry;

15 (9) to promote cessation to reduce disease risk
16 and the social costs associated with tobacco-related
17 diseases; and

18 (10) to strengthen legislation against illicit
19 trade in tobacco products.

20 **SEC. 4. SCOPE AND EFFECT.**

21 (a) INTENDED EFFECT.—Nothing in this Act (or an
22 amendment made by this Act) shall be construed to—

23 (1) establish a precedent with regard to any
24 other industry, situation, circumstance, or legal ac-
25 tion; or

1 (2) affect any action pending in Federal, State,
2 or Tribal court, or any agreement, consent decree, or
3 contract of any kind.

4 (b) AGRICULTURAL ACTIVITIES.—The provisions of
5 this Act (or an amendment made by this Act) which au-
6 thorize the Secretary to take certain actions with regard
7 to tobacco and tobacco products shall not be construed to
8 affect any authority of the Secretary of Agriculture under
9 existing law regarding the growing, cultivation, or curing
10 of raw tobacco.

11 (c) REVENUE ACTIVITIES.—The provisions of this
12 Act (or an amendment made by this Act) which authorize
13 the Secretary to take certain actions with regard to to-
14 bacco products shall not be construed to affect any author-
15 ity of the Secretary of the Treasury under chapter 52 of
16 the Internal Revenue Code of 1986.

17 **SEC. 5. SEVERABILITY.**

18 If any provision of this Act, the amendments made
19 by this Act, or the application of any provision of this Act
20 to any person or circumstance is held to be invalid, the
21 remainder of this Act, the amendments made by this Act,
22 and the application of the provisions of this Act to any
23 other person or circumstance shall not be affected and
24 shall continue to be enforced to the fullest extent possible.

1 **TITLE I—AUTHORITY OF THE**
2 **FOOD AND DRUG ADMINIS-**
3 **TRATION**

4 **SEC. 101. AMENDMENT OF FEDERAL FOOD, DRUG, AND**
5 **COSMETIC ACT.**

6 (a) DEFINITION OF TOBACCO PRODUCTS.—Section
7 201 of the Federal Food, Drug, and Cosmetic Act (21
8 U.S.C. 321) is amended by adding at the end the fol-
9 lowing:

10 “(rr)(1) The term ‘tobacco product’ means any prod-
11 uct made or derived from tobacco that is intended for
12 human consumption, including any component, part, or
13 accessory of a tobacco product (except for raw materials
14 other than tobacco used in manufacturing a component,
15 part, or accessory of a tobacco product).

16 “(2) The term ‘tobacco product’ does not mean an
17 article that is a drug under subsection (g)(1), a device
18 under subsection (h), or a combination product described
19 in section 503(g).

20 “(3) The products described in paragraph (2) shall
21 be subject to chapter V of this Act.

22 “(4) A tobacco product shall not be marketed in com-
23 bination with any other article or product regulated under
24 this Act (including a drug, biologic, food, cosmetic, med-
25 ical device, or a dietary supplement).”.

1 (b) FDA AUTHORITY OVER TOBACCO PRODUCTS.—
2 The Federal Food, Drug, and Cosmetic Act (21 U.S.C.
3 301 et seq.) is amended—

4 (1) by redesignating chapter IX as chapter X;

5 (2) by redesignating sections 901 through 910
6 as sections 1001 through 1010; and

7 (3) by inserting after chapter VIII the fol-
8 lowing:

9 **“CHAPTER IX—TOBACCO PRODUCTS**

10 **“SEC. 900. DEFINITIONS.**

11 “In this chapter:

12 “(1) ADDITIVE.—The term ‘additive’ means
13 any substance the intended use of which results or
14 may reasonably be expected to result, directly or in-
15 directly, in its becoming a component or otherwise
16 affecting the characteristic of any tobacco product
17 (including any substances intended for use as a fla-
18 voring or coloring or in producing, manufacturing,
19 packing, processing, preparing, treating, packaging,
20 transporting, or holding), except that such term does
21 not include tobacco or a pesticide chemical residue
22 in or on raw tobacco or a pesticide chemical.

23 “(2) BRAND.—The term ‘brand’ means a vari-
24 ety of tobacco product distinguished by the tobacco
25 used, tar content, nicotine content, flavoring used,

1 size, filtration, packaging, logo, registered trade-
2 mark, brand name, identifiable pattern of colors, or
3 any combination of such attributes.

4 “(3) CIGARETTE.—The term ‘cigarette’—

5 “(A) means a product that—

6 “(i) is a tobacco product; and

7 “(ii) meets the definition of the term
8 ‘cigarette’ in section 3(1) of the Federal
9 Cigarette Labeling and Advertising Act;
10 and

11 “(B) includes tobacco, in any form, that is
12 functional in the product, which, because of its
13 appearance, the type of tobacco used in the
14 filler, or its packaging and labeling, is likely to
15 be offered to, or purchased by, consumers as a
16 cigarette or as roll-your-own tobacco.

17 “(4) CIGARETTE TOBACCO.—The term ‘ciga-
18 rette tobacco’ means any product that consists of
19 loose tobacco that is intended for use by consumers
20 in a cigarette. Unless otherwise stated, the require-
21 ments applicable to cigarettes under this chapter
22 shall also apply to cigarette tobacco.

23 “(5) COMMERCE.—The term ‘commerce’ has
24 the meaning given that term by section 3(2) of the
25 Federal Cigarette Labeling and Advertising Act.

1 “(6) COUNTERFEIT TOBACCO PRODUCT.—The
2 term ‘counterfeit tobacco product’ means a tobacco
3 product (or the container or labeling of such a prod-
4 uct) that, without authorization, bears the trade-
5 mark, trade name, or other identifying mark, im-
6 print, or device, or any likeness thereof, of a tobacco
7 product listed in a registration under section
8 905(i)(1).

9 “(7) DISTRIBUTOR.—The term ‘distributor’ as
10 regards a tobacco product means any person who
11 furthers the distribution of a tobacco product,
12 whether domestic or imported, at any point from the
13 original place of manufacture to the person who sells
14 or distributes the product to individuals for personal
15 consumption. Common carriers are not considered
16 distributors for purposes of this chapter.

17 “(8) ILLICIT TRADE.—The term ‘illicit trade’
18 means any practice or conduct prohibited by law
19 which relates to production, shipment, receipt, pos-
20 session, distribution, sale, or purchase of tobacco
21 products including any practice or conduct intended
22 to facilitate such activity.

23 “(9) INDIAN COUNTRY.—The term ‘Indian
24 country’ has the meaning given such term in section
25 1151 of title 18, United States Code.

1 “(10) INDIAN TRIBE.—The term ‘Indian tribe’
2 has the meaning given such term in section 4(e) of
3 the Indian Self-Determination and Education Assist-
4 ance Act.

5 “(11) LITTLE CIGAR.—The term ‘little cigar’
6 means a product that—

7 “(A) is a tobacco product; and

8 “(B) meets the definition of the term ‘little
9 cigar’ in section 3(7) of the Federal Cigarette
10 Labeling and Advertising Act.

11 “(12) NICOTINE.—The term ‘nicotine’ means
12 the chemical substance named 3-(1-Methyl-2-
13 pyrrolidinyl) pyridine or C[10]H[14]N[2], including
14 any salt or complex of nicotine.

15 “(13) PACKAGE.—The term ‘package’ means a
16 pack, box, carton, or container of any kind or, if no
17 other container, any wrapping (including cello-
18 phane), in which a tobacco product is offered for
19 sale, sold, or otherwise distributed to consumers.

20 “(14) RETAILER.—The term ‘retailer’ means
21 any person, government, or entity who sells tobacco
22 products to individuals for personal consumption, or
23 who operates a facility where self-service displays of
24 tobacco products are permitted.

1 “(15) ROLL-YOUR-OWN TOBACCO.—The term
2 ‘roll-your-own tobacco’ means any tobacco product
3 which, because of its appearance, type, packaging, or
4 labeling, is suitable for use and likely to be offered
5 to, or purchased by, consumers as tobacco for mak-
6 ing cigarettes.

7 “(16) SMALL TOBACCO PRODUCT MANUFAC-
8 TURER.—The term ‘small tobacco product manufac-
9 turer’ means a tobacco product manufacturer that
10 employs fewer than 350 employees. For purposes of
11 determining the number of employees of a manufac-
12 turer under the preceding sentence, the employees of
13 a manufacturer are deemed to include the employees
14 of each entity that controls, is controlled by, or is
15 under common control with such manufacturer.

16 “(17) SMOKE CONSTITUENT.—The term ‘smoke
17 constituent’ means any chemical or chemical com-
18 pound in mainstream or sidestream tobacco smoke
19 that either transfers from any component of the cig-
20 arette to the smoke or that is formed by the combus-
21 tion or heating of tobacco, additives, or other compo-
22 nent of the tobacco product.

23 “(18) SMOKELESS TOBACCO.—The term
24 ‘smokeless tobacco’ means any tobacco product that
25 consists of cut, ground, powdered, or leaf tobacco

1 and that is intended to be placed in the oral or nasal
2 cavity.

3 “(19) STATE; TERRITORY.—The terms ‘State’
4 and ‘Territory’ shall have the meanings given to
5 such terms in section 201.

6 “(20) TOBACCO PRODUCT MANUFACTURER.—
7 The term ‘tobacco product manufacturer’ means any
8 person, including any repacker or relabeler, who—

9 “(A) manufactures, fabricates, assembles,
10 processes, or labels a tobacco product; or

11 “(B) imports a finished tobacco product
12 for sale or distribution in the United States.

13 “(21) TOBACCO WAREHOUSE.—

14 “(A) Subject to subparagraphs (B) and
15 (C), the term ‘tobacco warehouse’ includes any
16 person—

17 “(i) who—

18 “(I) removes foreign material
19 from tobacco leaf through nothing
20 other than a mechanical process;

21 “(II) humidifies tobacco leaf with
22 nothing other than potable water in
23 the form of steam or mist; or

24 “(III) de-stems, dries, and packs
25 tobacco leaf for storage and shipment;

1 “(ii) who performs no other actions
2 with respect to tobacco leaf; and

3 “(iii) who provides to any manufac-
4 turer to whom the person sells tobacco all
5 information related to the person’s actions
6 described in clause (i) that is necessary for
7 compliance with this Act.

8 “(B) The term ‘tobacco warehouse’ ex-
9 cludes any person who—

10 “(i) reconstitutes tobacco leaf;

11 “(ii) is a manufacturer, distributor, or
12 retailer of a tobacco product; or

13 “(iii) applies any chemical, additive,
14 or substance to the tobacco leaf other than
15 potable water in the form of steam or mist.

16 “(C) The definition of the term ‘tobacco
17 warehouse’ in subparagraph (A) shall not apply
18 to the extent to which the Secretary determines,
19 through rulemaking, that regulation under this
20 chapter of the actions described in such sub-
21 paragraph is appropriate for the protection of
22 the public health.

23 “(22) UNITED STATES.—The term ‘United
24 States’ means the 50 States of the United States of
25 America and the District of Columbia, the Common-

1 wealth of Puerto Rico, Guam, the Virgin Islands,
2 American Samoa, Wake Island, Midway Islands,
3 Kingman Reef, Johnston Atoll, the Northern Mar-
4 iana Islands, and any other trust territory or posses-
5 sion of the United States.

6 **“SEC. 901. FDA AUTHORITY OVER TOBACCO PRODUCTS.**

7 “(a) IN GENERAL.—Tobacco products, including
8 modified risk tobacco products for which an order has
9 been issued in accordance with section 911, shall be regu-
10 lated by the Secretary under this chapter and shall not
11 be subject to the provisions of chapter V.

12 “(b) APPLICABILITY.—This chapter shall apply to all
13 cigarettes, cigarette tobacco, roll-your-own tobacco, and
14 smokeless tobacco and to any other tobacco products that
15 the Secretary by regulation deems to be subject to this
16 chapter.

17 “(c) SCOPE.—

18 “(1) IN GENERAL.—Nothing in this chapter, or
19 any policy issued or regulation promulgated there-
20 under, or in sections 101(a), 102, or 103 of title I,
21 title II, or title III of the Family Smoking Preven-
22 tion and Tobacco Control Act, shall be construed to
23 affect, expand, or limit the Secretary’s authority
24 over (including the authority to determine whether
25 products may be regulated), or the regulation of,

1 products under this Act that are not tobacco prod-
2 ucts under chapter V or any other chapter.

3 “(2) LIMITATION OF AUTHORITY.—

4 “(A) IN GENERAL.—The provisions of this
5 chapter shall not apply to tobacco leaf that is
6 not in the possession of a manufacturer of to-
7 bacco products, or to the producers of tobacco
8 leaf, including tobacco growers, tobacco ware-
9 houses, and tobacco grower cooperatives, nor
10 shall any employee of the Food and Drug Ad-
11 ministration have any authority to enter onto a
12 farm owned by a producer of tobacco leaf with-
13 out the written consent of such producer.

14 “(B) EXCEPTION.—Notwithstanding sub-
15 paragraph (A), if a producer of tobacco leaf is
16 also a tobacco product manufacturer or con-
17 trolled by a tobacco product manufacturer, the
18 producer shall be subject to this chapter in the
19 producer’s capacity as a manufacturer. The ex-
20 ception in this subparagraph shall not apply to
21 a producer of tobacco leaf who grows tobacco
22 under a contract with a tobacco product manu-
23 facturer and who is not otherwise engaged in
24 the manufacturing process.

1 “(C) RULE OF CONSTRUCTION.—Nothing
2 in this chapter shall be construed to grant the
3 Secretary authority to promulgate regulations
4 on any matter that involves the production of
5 tobacco leaf or a producer thereof, other than
6 activities by a manufacturer affecting produc-
7 tion.

8 “(d) RULEMAKING PROCEDURES.—Each rulemaking
9 under this chapter shall be in accordance with chapter 5
10 of title 5, United States Code. This subsection shall not
11 be construed to affect the rulemaking provisions of section
12 102(a) of the Family Smoking Prevention and Tobacco
13 Control Act.

14 “(e) CENTER FOR TOBACCO PRODUCTS.—Not later
15 than 90 days after the date of enactment of the Family
16 Smoking Prevention and Tobacco Control Act, the Sec-
17 retary shall establish within the Food and Drug Adminis-
18 tration the Center for Tobacco Products, which shall re-
19 port to the Commissioner of Food and Drugs in the same
20 manner as the other agency centers within the Food and
21 Drug Administration. The Center shall be responsible for
22 the implementation of this chapter and related matters as-
23 signed by the Commissioner.

24 “(f) OFFICE TO ASSIST SMALL TOBACCO PRODUCT
25 MANUFACTURERS.—The Secretary shall establish within

1 the Food and Drug Administration an identifiable office
2 to provide technical and other nonfinancial assistance to
3 small tobacco product manufacturers to assist them in
4 complying with the requirements of this Act.

5 “(g) CONSULTATION PRIOR TO RULEMAKING.—Prior
6 to promulgating rules under this chapter, the Secretary
7 shall endeavor to consult with other Federal agencies as
8 appropriate.

9 **“SEC. 902. ADULTERATED TOBACCO PRODUCTS.**

10 “A tobacco product shall be deemed to be adulterated
11 if—

12 “(1) it consists in whole or in part of any filthy,
13 putrid, or decomposed substance, or is otherwise
14 contaminated by any added poisonous or added dele-
15 terious substance that may render the product inju-
16 rious to health;

17 “(2) it has been prepared, packed, or held
18 under insanitary conditions whereby it may have
19 been contaminated with filth, or whereby it may
20 have been rendered injurious to health;

21 “(3) its package is composed, in whole or in
22 part, of any poisonous or deleterious substance
23 which may render the contents injurious to health;

24 “(4) the manufacturer or importer of the to-
25 bacco product fails to pay a user fee assessed to

1 such manufacturer or importer pursuant to section
2 919 by the date specified in section 919 or by the
3 30th day after final agency action on a resolution of
4 any dispute as to the amount of such fee;

5 “(5) it is, or purports to be or is represented
6 as, a tobacco product which is subject to a tobacco
7 product standard established under section 907 un-
8 less such tobacco product is in all respects in con-
9 formity with such standard;

10 “(6)(A) it is required by section 910(a) to have
11 premarket review and does not have an order in ef-
12 fect under section 910(c)(1)(A)(i); or

13 “(B) it is in violation of an order under section
14 910(c)(1)(A);

15 “(7) the methods used in, or the facilities or
16 controls used for, its manufacture, packing, or stor-
17 age are not in conformity with applicable require-
18 ments under section 906(e)(1) or an applicable con-
19 dition prescribed by an order under section
20 906(e)(2); or

21 “(8) it is in violation of section 911.

22 **“SEC. 903. MISBRANDED TOBACCO PRODUCTS.**

23 “(a) IN GENERAL.—A tobacco product shall be
24 deemed to be misbranded—

1 “(1) if its labeling is false or misleading in any
2 particular;

3 “(2) if in package form unless it bears a label
4 containing—

5 “(A) the name and place of business of the
6 tobacco product manufacturer, packer, or dis-
7 tributor;

8 “(B) an accurate statement of the quantity
9 of the contents in terms of weight, measure, or
10 numerical count;

11 “(C) an accurate statement of the percent-
12 age of the tobacco used in the product that is
13 domestically grown tobacco and the percentage
14 that is foreign grown tobacco; and

15 “(D) the statement required under section
16 920(a),

17 except that under subparagraph (B) reasonable vari-
18 ations shall be permitted, and exemptions as to
19 small packages shall be established, by regulations
20 prescribed by the Secretary;

21 “(3) if any word, statement, or other informa-
22 tion required by or under authority of this chapter
23 to appear on the label or labeling is not prominently
24 placed thereon with such conspicuousness (as com-
25 pared with other words, statements, or designs in

1 the labeling) and in such terms as to render it likely
2 to be read and understood by the ordinary individual
3 under customary conditions of purchase and use;

4 “(4) if it has an established name, unless its
5 label bears, to the exclusion of any other nonpropri-
6 etary name, its established name prominently print-
7 ed in type as required by the Secretary by regula-
8 tion;

9 “(5) if the Secretary has issued regulations re-
10 quiring that its labeling bear adequate directions for
11 use, or adequate warnings against use by children,
12 that are necessary for the protection of users unless
13 its labeling conforms in all respects to such regula-
14 tions;

15 “(6) if it was manufactured, prepared, propa-
16 gated, compounded, or processed in an establishment
17 not duly registered under section 905(b), 905(c),
18 905(d), or 905(h), if it was not included in a list re-
19 quired by section 905(i), if a notice or other infor-
20 mation respecting it was not provided as required by
21 such section or section 905(j), or if it does not bear
22 such symbols from the uniform system for identifica-
23 tion of tobacco products prescribed under section
24 905(e) as the Secretary by regulation requires;

1 “(7) if, in the case of any tobacco product dis-
2 tributed or offered for sale in any State—

3 “(A) its advertising is false or misleading
4 in any particular; or

5 “(B) it is sold or distributed in violation of
6 regulations prescribed under section 906(d);

7 “(8) unless, in the case of any tobacco product
8 distributed or offered for sale in any State, the man-
9 ufacturer, packer, or distributor thereof includes in
10 all advertisements and other descriptive printed mat-
11 ter issued or caused to be issued by the manufac-
12 turer, packer, or distributor with respect to that to-
13 bacco product—

14 “(A) a true statement of the tobacco prod-
15 uct’s established name as described in para-
16 graph (4), printed prominently; and

17 “(B) a brief statement of—

18 “(i) the uses of the tobacco product
19 and relevant warnings, precautions, side
20 effects, and contraindications; and

21 “(ii) in the case of specific tobacco
22 products made subject to a finding by the
23 Secretary after notice and opportunity for
24 comment that such action is appropriate to
25 protect the public health, a full description

1 of the components of such tobacco product
2 or the formula showing quantitatively each
3 ingredient of such tobacco product to the
4 extent required in regulations which shall
5 be issued by the Secretary after an oppor-
6 tunity for a hearing;

7 “(9) if it is a tobacco product subject to a to-
8 bacco product standard established under section
9 907, unless it bears such labeling as may be pre-
10 scribed in such tobacco product standard; or

11 “(10) if there was a failure or refusal—

12 “(A) to comply with any requirement pre-
13 scribed under section 904 or 908; or

14 “(B) to furnish any material or informa-
15 tion required under section 909.

16 “(b) PRIOR APPROVAL OF LABEL STATEMENTS.—

17 The Secretary may, by regulation, require prior approval
18 of statements made on the label of a tobacco product. No
19 regulation issued under this subsection may require prior
20 approval by the Secretary of the content of any advertise-
21 ment, except for modified risk tobacco products as pro-
22 vided in section 911. No advertisement of a tobacco prod-
23 uct published after the date of enactment of the Family
24 Smoking Prevention and Tobacco Control Act shall, with
25 respect to the language of label statements as prescribed

1 under section 4 of the Federal Cigarette Labeling and Ad-
2 vertising Act and section 3 of the Comprehensive Smoke-
3 less Tobacco Health Education Act of 1986 or the regula-
4 tions issued under such sections, be subject to the provi-
5 sions of sections 12 through 15 of the Federal Trade Com-
6 mission Act.

7 **“SEC. 904. SUBMISSION OF HEALTH INFORMATION TO THE**
8 **SECRETARY.**

9 “(a) REQUIREMENT.—Each tobacco product manu-
10 facturer or importer, or agents thereof, shall submit to
11 the Secretary the following information:

12 “(1) Not later than 6 months after the date of
13 enactment of the Family Smoking Prevention and
14 Tobacco Control Act, a listing of all ingredients, in-
15 cluding tobacco, substances, compounds, and addi-
16 tives that are, as of such date, added by the manu-
17 facturer to the tobacco, paper, filter, or other part
18 of each tobacco product by brand and by quantity in
19 each brand and subbrand.

20 “(2) A description of the content, delivery, and
21 form of nicotine in each tobacco product measured
22 in milligrams of nicotine in accordance with regula-
23 tions promulgated by the Secretary in accordance
24 with section 4(e) of the Federal Cigarette Labeling
25 and Advertising Act.

1 “(3) Beginning 3 years after the date of enact-
2 ment of the Family Smoking Prevention and To-
3 bacco Control Act, a listing of all constituents, in-
4 cluding smoke constituents as applicable, identified
5 by the Secretary as harmful or potentially harmful
6 to health in each tobacco product, and as applicable
7 in the smoke of each tobacco product, by brand and
8 by quantity in each brand and subbrand. Effective
9 beginning 3 years after such date of enactment, the
10 manufacturer, importer, or agent shall comply with
11 regulations promulgated under section 915 in re-
12 porting information under this paragraph, where ap-
13 plicable.

14 “(4) Beginning 6 months after the date of en-
15 actment of the Family Smoking Prevention and To-
16 bacco Control Act, all documents developed after
17 such date of enactment that relate to health, toxi-
18 cological, behavioral, or physiologic effects of current
19 or future tobacco products, their constituents (in-
20 cluding smoke constituents), ingredients, compo-
21 nents, and additives.

22 “(b) DATA SUBMISSION.—At the request of the Sec-
23 retary, each tobacco product manufacturer or importer of
24 tobacco products, or agents thereof, shall submit the fol-
25 lowing:

1 “(1) Any or all documents (including under-
2 lying scientific information) relating to research ac-
3 tivities, and research findings, conducted, supported,
4 or possessed by the manufacturer (or agents thereof)
5 on the health, toxicological, behavioral, or physio-
6 logic effects of tobacco products and their constitu-
7 ents (including smoke constituents), ingredients,
8 components, and additives.

9 “(2) Any or all documents (including under-
10 lying scientific information) relating to research ac-
11 tivities, and research findings, conducted, supported,
12 or possessed by the manufacturer (or agents thereof)
13 that relate to the issue of whether a reduction in
14 risk to health from tobacco products can occur upon
15 the employment of technology available or known to
16 the manufacturer.

17 “(3) Any or all documents (including under-
18 lying scientific or financial information) relating to
19 marketing research involving the use of tobacco
20 products or marketing practices and the effective-
21 ness of such practices used by tobacco manufactur-
22 ers and distributors.

23 An importer of a tobacco product not manufactured in the
24 United States shall supply the information required of a
25 tobacco product manufacturer under this subsection.

1 “(c) TIME FOR SUBMISSION.—

2 “(1) IN GENERAL.—At least 90 days prior to
3 the delivery for introduction into interstate com-
4 merce of a tobacco product not on the market on the
5 date of enactment of the Family Smoking Preven-
6 tion and Tobacco Control Act, the manufacturer of
7 such product shall provide the information required
8 under subsection (a).

9 “(2) DISCLOSURE OF ADDITIVE.—If at any
10 time a tobacco product manufacturer adds to its to-
11 bacco products a new tobacco additive or increases
12 the quantity of an existing tobacco additive, the
13 manufacturer shall, except as provided in paragraph
14 (3), at least 90 days prior to such action so advise
15 the Secretary in writing.

16 “(3) DISCLOSURE OF OTHER ACTIONS.—If at
17 any time a tobacco product manufacturer eliminates
18 or decreases an existing additive, or adds or in-
19 creases an additive that has by regulation been des-
20 ignated by the Secretary as an additive that is not
21 a human or animal carcinogen, or otherwise harmful
22 to health under intended conditions of use, the man-
23 ufacturer shall within 60 days of such action so ad-
24 vise the Secretary in writing.

25 “(d) DATA LIST.—

1 “(1) IN GENERAL.—Not later than 3 years
2 after the date of enactment of the Family Smoking
3 Prevention and Tobacco Control Act, and annually
4 thereafter, the Secretary shall publish in a format
5 that is understandable and not misleading to a lay
6 person, and place on public display (in a manner de-
7 termined by the Secretary) the list established under
8 subsection (e).

9 “(2) CONSUMER RESEARCH.—The Secretary
10 shall conduct periodic consumer research to ensure
11 that the list published under paragraph (1) is not
12 misleading to lay persons. Not later than 5 years
13 after the date of enactment of the Family Smoking
14 Prevention and Tobacco Control Act, the Secretary
15 shall submit to the appropriate committees of Con-
16 gress a report on the results of such research, to-
17 gether with recommendations on whether such publi-
18 cation should be continued or modified.

19 “(e) DATA COLLECTION.—Not later than 24 months
20 after the date of enactment of the Family Smoking Pre-
21 vention and Tobacco Control Act, the Secretary shall es-
22 tablish, and periodically revise as appropriate, a list of
23 harmful and potentially harmful constituents, including
24 smoke constituents, to health in each tobacco product by
25 brand and by quantity in each brand and subbrand. The

1 Secretary shall publish a public notice requesting the sub-
2 mission by interested persons of scientific and other infor-
3 mation concerning the harmful and potentially harmful
4 constituents in tobacco products and tobacco smoke.

5 **“SEC. 905. ANNUAL REGISTRATION.**

6 “(a) DEFINITIONS.—In this section:

7 “(1) MANUFACTURE, PREPARATION,
8 COMPOUNDING, OR PROCESSING.—The term ‘manu-
9 facture, preparation, compounding, or processing’
10 shall include repackaging or otherwise changing the
11 container, wrapper, or labeling of any tobacco prod-
12 uct package in furtherance of the distribution of the
13 tobacco product from the original place of manufac-
14 ture to the person who makes final delivery or sale
15 to the ultimate consumer or user.

16 “(2) NAME.—The term ‘name’ shall include in
17 the case of a partnership the name of each partner
18 and, in the case of a corporation, the name of each
19 corporate officer and director, and the State of in-
20 corporation.

21 “(b) REGISTRATION BY OWNERS AND OPERATORS.—
22 On or before December 31 of each year, every person who
23 owns or operates any establishment in any State engaged
24 in the manufacture, preparation, compounding, or proc-
25 essing of a tobacco product or tobacco products shall reg-

1 ister with the Secretary the name, places of business, and
2 all such establishments of that person. If enactment of the
3 Family Smoking Prevention and Tobacco Control Act oc-
4 curs in the second half of the calendar year, the Secretary
5 shall designate a date no later than 6 months into the
6 subsequent calendar year by which registration pursuant
7 to this subsection shall occur.

8 “(c) REGISTRATION BY NEW OWNERS AND OPERA-
9 TORS.—Every person upon first engaging in the manufac-
10 ture, preparation, compounding, or processing of a tobacco
11 product or tobacco products in any establishment owned
12 or operated in any State by that person shall immediately
13 register with the Secretary that person’s name, place of
14 business, and such establishment.

15 “(d) REGISTRATION OF ADDED ESTABLISHMENTS.—
16 Every person required to register under subsection (b) or
17 (c) shall immediately register with the Secretary any addi-
18 tional establishment which that person owns or operates
19 in any State and in which that person begins the manufac-
20 ture, preparation, compounding, or processing of a tobacco
21 product or tobacco products.

22 “(e) UNIFORM PRODUCT IDENTIFICATION SYS-
23 TEM.—The Secretary may by regulation prescribe a uni-
24 form system for the identification of tobacco products and
25 may require that persons who are required to list such

1 tobacco products under subsection (i) shall list such to-
2 bacco products in accordance with such system.

3 “(f) PUBLIC ACCESS TO REGISTRATION INFORMA-
4 TION.—The Secretary shall make available for inspection,
5 to any person so requesting, any registration filed under
6 this section.

7 “(g) BIENNIAL INSPECTION OF REGISTERED ESTAB-
8 LISHMENTS.—Every establishment registered with the
9 Secretary under this section shall be subject to inspection
10 under section 704 or subsection (h), and every such estab-
11 lishment engaged in the manufacture, compounding, or
12 processing of a tobacco product or tobacco products shall
13 be so inspected by 1 or more officers or employees duly
14 designated by the Secretary at least once in the 2-year
15 period beginning with the date of registration of such es-
16 tablishment under this section and at least once in every
17 successive 2-year period thereafter.

18 “(h) REGISTRATION BY FOREIGN ESTABLISH-
19 MENTS.—Any establishment within any foreign country
20 engaged in the manufacture, preparation, compounding,
21 or processing of a tobacco product or tobacco products,
22 shall register under this section under regulations promul-
23 gated by the Secretary. Such regulations shall require
24 such establishment to provide the information required by
25 subsection (i) and shall include provisions for registration

1 of any such establishment upon condition that adequate
2 and effective means are available, by arrangement with the
3 government of such foreign country or otherwise, to enable
4 the Secretary to determine from time to time whether to-
5 bacco products manufactured, prepared, compounded, or
6 processed in such establishment, if imported or offered for
7 import into the United States, shall be refused admission
8 on any of the grounds set forth in section 801(a).

9 “(i) REGISTRATION INFORMATION.—

10 “(1) PRODUCT LIST.—Every person who reg-
11 isters with the Secretary under subsection (b), (c),
12 (d), or (h) shall, at the time of registration under
13 any such subsection, file with the Secretary a list of
14 all tobacco products which are being manufactured,
15 prepared, compounded, or processed by that person
16 for commercial distribution and which have not been
17 included in any list of tobacco products filed by that
18 person with the Secretary under this paragraph or
19 paragraph (2) before such time of registration. Such
20 list shall be prepared in such form and manner as
21 the Secretary may prescribe and shall be accom-
22 panied by—

23 “(A) in the case of a tobacco product con-
24 tained in the applicable list with respect to
25 which a tobacco product standard has been es-

1 tablished under section 907 or which is subject
2 to section 910, a reference to the authority for
3 the marketing of such tobacco product and a
4 copy of all labeling for such tobacco product;

5 “(B) in the case of any other tobacco prod-
6 uct contained in an applicable list, a copy of all
7 consumer information and other labeling for
8 such tobacco product, a representative sampling
9 of advertisements for such tobacco product,
10 and, upon request made by the Secretary for
11 good cause, a copy of all advertisements for a
12 particular tobacco product; and

13 “(C) if the registrant filing a list has de-
14 termined that a tobacco product contained in
15 such list is not subject to a tobacco product
16 standard established under section 907, a brief
17 statement of the basis upon which the reg-
18 istrant made such determination if the Sec-
19 retary requests such a statement with respect
20 to that particular tobacco product.

21 “(2) CONSULTATION WITH RESPECT TO
22 FORMS.—The Secretary shall consult with the Sec-
23 retary of the Treasury in developing the forms to be
24 used for registration under this section to minimize
25 the burden on those persons required to register

1 with both the Secretary and the Tax and Trade Bu-
2 reau of the Department of the Treasury.

3 “(3) BIENNIAL REPORT OF ANY CHANGE IN
4 PRODUCT LIST.—Each person who registers with the
5 Secretary under this section shall report to the Sec-
6 retary once during the month of June of each year
7 and once during the month of December of each
8 year the following:

9 “(A) A list of each tobacco product intro-
10 duced by the registrant for commercial distribu-
11 tion which has not been included in any list
12 previously filed by that person with the Sec-
13 retary under this subparagraph or paragraph
14 (1). A list under this subparagraph shall list a
15 tobacco product by its established name and
16 shall be accompanied by the other information
17 required by paragraph (1).

18 “(B) If since the date the registrant last
19 made a report under this paragraph that person
20 has discontinued the manufacture, preparation,
21 compounding, or processing for commercial dis-
22 tribution of a tobacco product included in a list
23 filed under subparagraph (A) or paragraph (1),
24 notice of such discontinuance, the date of such

1 discontinuance, and the identity of its estab-
2 lished name.

3 “(C) If since the date the registrant re-
4 ported under subparagraph (B) a notice of dis-
5 continuance that person has resumed the manu-
6 facture, preparation, compounding, or proc-
7 essing for commercial distribution of the to-
8 bacco product with respect to which such notice
9 of discontinuance was reported, notice of such
10 resumption, the date of such resumption, the
11 identity of such tobacco product by established
12 name, and other information required by para-
13 graph (1), unless the registrant has previously
14 reported such resumption to the Secretary
15 under this subparagraph.

16 “(D) Any material change in any informa-
17 tion previously submitted under this paragraph
18 or paragraph (1).

19 “(j) REPORT PRECEDING INTRODUCTION OF CER-
20 TAIN SUBSTANTIALLY EQUIVALENT PRODUCTS INTO
21 INTERSTATE COMMERCE.—

22 “(1) IN GENERAL.—Each person who is re-
23 quired to register under this section and who pro-
24 poses to begin the introduction or delivery for intro-
25 duction into interstate commerce for commercial dis-

1 tribution of a tobacco product intended for human
2 use that was not commercially marketed (other than
3 for test marketing) in the United States as of Feb-
4 ruary 15, 2007, shall, at least 90 days prior to mak-
5 ing such introduction or delivery, report to the Sec-
6 retary (in such form and manner as the Secretary
7 shall prescribe)—

8 “(A) the basis for such person’s determina-
9 tion that—

10 “(i) the tobacco product is substan-
11 tially equivalent, within the meaning of
12 section 910, to a tobacco product commer-
13 cially marketed (other than for test mar-
14 keting) in the United States as of Feb-
15 ruary 15, 2007, or to a tobacco product
16 that the Secretary has previously deter-
17 mined, pursuant to subsection (a)(3) of
18 section 910, is substantially equivalent and
19 that is in compliance with the require-
20 ments of this Act; or

21 “(ii) the tobacco product is modified
22 within the meaning of paragraph (3), the
23 modifications are to a product that is com-
24 mercially marketed and in compliance with
25 the requirements of this Act, and all of the

1 modifications are covered by exemptions
2 granted by the Secretary pursuant to para-
3 graph (3); and

4 “(B) action taken by such person to com-
5 ply with the requirements under section 907
6 that are applicable to the tobacco product.

7 “(2) APPLICATION TO CERTAIN POST-FEB-
8 RUARY 15, 2007, PRODUCTS.—A report under this
9 subsection for a tobacco product that was first intro-
10 duced or delivered for introduction into interstate
11 commerce for commercial distribution in the United
12 States after February 15, 2007, and prior to the
13 date that is 21 months after the date of enactment
14 of the Family Smoking Prevention and Tobacco
15 Control Act shall be submitted to the Secretary not
16 later than 21 months after such date of enactment.

17 “(3) EXEMPTIONS.—

18 “(A) IN GENERAL.—The Secretary may
19 exempt from the requirements of this sub-
20 section relating to the demonstration that a to-
21 bacco product is substantially equivalent within
22 the meaning of section 910, tobacco products
23 that are modified by adding or deleting a to-
24 bacco additive, or increasing or decreasing the

1 quantity of an existing tobacco additive, if the
2 Secretary determines that—

3 “(i) such modification would be a
4 minor modification of a tobacco product
5 that can be sold under this Act;

6 “(ii) a report under this subsection is
7 not necessary to ensure that permitting the
8 tobacco product to be marketed would be
9 appropriate for protection of the public
10 health; and

11 “(iii) an exemption is otherwise appro-
12 priate.

13 “(B) REGULATIONS.—Not later than 15
14 months after the date of enactment of the Fam-
15 ily Smoking Prevention and Tobacco Control
16 Act, the Secretary shall issue regulations to im-
17 plement this paragraph.

18 **“SEC. 906. GENERAL PROVISIONS RESPECTING CONTROL**
19 **OF TOBACCO PRODUCTS.**

20 “(a) IN GENERAL.—Any requirement established by
21 or under section 902, 903, 905, or 909 applicable to a
22 tobacco product shall apply to such tobacco product until
23 the applicability of the requirement to the tobacco product
24 has been changed by action taken under section 907, sec-
25 tion 910, section 911, or subsection (d) of this section,

1 and any requirement established by or under section 902,
2 903, 905, or 909 which is inconsistent with a requirement
3 imposed on such tobacco product under section 907, sec-
4 tion 910, section 911, or subsection (d) of this section
5 shall not apply to such tobacco product.

6 “(b) INFORMATION ON PUBLIC ACCESS AND COM-
7 MENT.—Each notice of proposed rulemaking or other noti-
8 fication under section 907, 908, 909, 910, or 911 or under
9 this section, any other notice which is published in the
10 Federal Register with respect to any other action taken
11 under any such section and which states the reasons for
12 such action, and each publication of findings required to
13 be made in connection with rulemaking under any such
14 section shall set forth—

15 “(1) the manner in which interested persons
16 may examine data and other information on which
17 the notice or findings is based; and

18 “(2) the period within which interested persons
19 may present their comments on the notice or find-
20 ings (including the need therefore) orally or in writ-
21 ing, which period shall be at least 60 days but may
22 not exceed 90 days unless the time is extended by
23 the Secretary by a notice published in the Federal
24 Register stating good cause therefore.

1 “(c) LIMITED CONFIDENTIALITY OF INFORMA-
2 TION.—Any information reported to or otherwise obtained
3 by the Secretary or the Secretary’s representative under
4 section 903, 904, 907, 908, 909, 910, 911, or 704, or
5 under subsection (e) or (f) of this section, which is exempt
6 from disclosure under subsection (a) of section 552 of title
7 5, United States Code, by reason of subsection (b)(4) of
8 that section shall be considered confidential and shall not
9 be disclosed, except that the information may be disclosed
10 to other officers or employees concerned with carrying out
11 this chapter, or when relevant in any proceeding under
12 this chapter.

13 “(d) RESTRICTIONS.—

14 “(1) IN GENERAL.—The Secretary may by reg-
15 ulation require restrictions on the sale and distribu-
16 tion of a tobacco product, including restrictions on
17 the access to, and the advertising and promotion of,
18 the tobacco product, if the Secretary determines that
19 such regulation would be appropriate for the protec-
20 tion of the public health. The Secretary may by reg-
21 ulation impose restrictions on the advertising and
22 promotion of a tobacco product consistent with and
23 to full extent permitted by the first amendment to
24 the Constitution. The finding as to whether such
25 regulation would be appropriate for the protection of

1 the public health shall be determined with respect to
2 the risks and benefits to the population as a whole,
3 including users and nonusers of the tobacco product,
4 and taking into account—

5 “(A) the increased or decreased likelihood
6 that existing users of tobacco products will stop
7 using such products; and

8 “(B) the increased or decreased likelihood
9 that those who do not use tobacco products will
10 start using such products.

11 No such regulation may require that the sale or dis-
12 tribution of a tobacco product be limited to the writ-
13 ten or oral authorization of a practitioner licensed
14 by law to prescribe medical products.

15 “(2) LABEL STATEMENTS.—The label of a to-
16 bacco product shall bear such appropriate state-
17 ments of the restrictions required by a regulation
18 under subsection (a) as the Secretary may in such
19 regulation prescribe.

20 “(3) LIMITATIONS.—

21 “(A) IN GENERAL.—No restrictions under
22 paragraph (1) may—

23 “(i) prohibit the sale of any tobacco
24 product in face-to-face transactions by a
25 specific category of retail outlets; or

1 “(ii) establish a minimum age of sale
2 of tobacco products to any person older
3 than 18 years of age.

4 “(B) MATCHBOOKS.—For purposes of any
5 regulations issued by the Secretary, matchbooks
6 of conventional size containing not more than
7 20 paper matches, and which are customarily
8 given away for free with the purchase of to-
9 bacco products, shall be considered as adult-
10 written publications which shall be permitted to
11 contain advertising. Notwithstanding the pre-
12 ceding sentence, if the Secretary finds that such
13 treatment of matchbooks is not appropriate for
14 the protection of the public health, the Sec-
15 retary may determine by regulation that match-
16 books shall not be considered adult-written pub-
17 lications.

18 “(4) REMOTE SALES.—

19 “(A) IN GENERAL.—The Secretary shall—

20 “(i) within 18 months after the date
21 of enactment of the Family Smoking Pre-
22 vention and Tobacco Control Act, promul-
23 gate regulations regarding the sale and
24 distribution of tobacco products that occur
25 through means other than a direct, face-to-

1 face exchange between a retailer and a
2 consumer in order to prevent the sale and
3 distribution of tobacco products to individ-
4 uals who have not attained the minimum
5 age established by applicable law for the
6 purchase of such products, including re-
7 quirements for age verification; and

8 “(ii) within 2 years after such date of
9 enactment, issue regulations to address the
10 promotion and marketing of tobacco prod-
11 ucts that are sold or distributed through
12 means other than a direct, face-to-face ex-
13 change between a retailer and a consumer
14 in order to protect individuals who have
15 not attained the minimum age established
16 by applicable law for the purchase of such
17 products.

18 “(B) RELATION TO OTHER AUTHORITY.—
19 Nothing in this paragraph limits the authority
20 of the Secretary to take additional actions
21 under the other paragraphs of this subsection.

22 “(e) GOOD MANUFACTURING PRACTICE REQUIRE-
23 MENTS.—

24 “(1) METHODS, FACILITIES, AND CONTROLS TO
25 CONFORM.—

1 “(A) IN GENERAL.—In applying manufac-
2 turing restrictions to tobacco, the Secretary
3 shall, in accordance with subparagraph (B),
4 prescribe regulations (which may differ based
5 on the type of tobacco product involved) requir-
6 ing that the methods used in, and the facilities
7 and controls used for, the manufacture,
8 preproduction design validation (including a
9 process to assess the performance of a tobacco
10 product), packing, and storage of a tobacco
11 product conform to current good manufacturing
12 practice, or hazard analysis and critical control
13 point methodology, as prescribed in such regu-
14 lations to assure that the public health is pro-
15 tected and that the tobacco product is in com-
16 pliance with this chapter. Such regulations may
17 provide for the testing of raw tobacco for pes-
18 ticide chemical residues regardless of whether a
19 tolerance for such chemical residues has been
20 established.

21 “(B) REQUIREMENTS.—The Secretary
22 shall—

23 “(i) before promulgating any regula-
24 tion under subparagraph (A), afford the
25 Tobacco Products Scientific Advisory Com-

1 mittee an opportunity to submit rec-
2 ommendations with respect to the regula-
3 tion proposed to be promulgated;

4 “(ii) before promulgating any regula-
5 tion under subparagraph (A), afford oppor-
6 tunity for an oral hearing;

7 “(iii) provide the Tobacco Products
8 Scientific Advisory Committee a reasonable
9 time to make its recommendation with re-
10 spect to proposed regulations under sub-
11 paragraph (A);

12 “(iv) in establishing the effective date
13 of a regulation promulgated under this
14 subsection, take into account the dif-
15 ferences in the manner in which the dif-
16 ferent types of tobacco products have his-
17 torically been produced, the financial re-
18 sources of the different tobacco product
19 manufacturers, and the state of their exist-
20 ing manufacturing facilities, and shall pro-
21 vide for a reasonable period of time for
22 such manufacturers to conform to good
23 manufacturing practices; and

24 “(v) not require any small tobacco
25 product manufacturer to comply with a

1 regulation under subparagraph (A) for at
2 least 4 years following the effective date
3 established by the Secretary for such regu-
4 lation.

5 “(2) EXEMPTIONS; VARIANCES.—

6 “(A) PETITION.—Any person subject to
7 any requirement prescribed under paragraph
8 (1) may petition the Secretary for a permanent
9 or temporary exemption or variance from such
10 requirement. Such a petition shall be submitted
11 to the Secretary in such form and manner as
12 the Secretary shall prescribe and shall—

13 “(i) in the case of a petition for an ex-
14 emption from a requirement, set forth the
15 basis for the petitioner’s determination
16 that compliance with the requirement is
17 not required to assure that the tobacco
18 product will be in compliance with this
19 chapter;

20 “(ii) in the case of a petition for a
21 variance from a requirement, set forth the
22 methods proposed to be used in, and the
23 facilities and controls proposed to be used
24 for, the manufacture, packing, and storage
25 of the tobacco product in lieu of the meth-

1 ods, facilities, and controls prescribed by
2 the requirement; and

3 “(iii) contain such other information
4 as the Secretary shall prescribe.

5 “(B) REFERRAL TO THE TOBACCO PROD-
6 UCTS SCIENTIFIC ADVISORY COMMITTEE.—The
7 Secretary may refer to the Tobacco Products
8 Scientific Advisory Committee any petition sub-
9 mitted under subparagraph (A). The Tobacco
10 Products Scientific Advisory Committee shall
11 report its recommendations to the Secretary
12 with respect to a petition referred to it within
13 60 days after the date of the petition’s referral.
14 Within 60 days after—

15 “(i) the date the petition was sub-
16 mitted to the Secretary under subpara-
17 graph (A); or

18 “(ii) the day after the petition was re-
19 ferred to the Tobacco Products Scientific
20 Advisory Committee,

21 whichever occurs later, the Secretary shall by
22 order either deny the petition or approve it.

23 “(C) APPROVAL.—The Secretary may ap-
24 prove—

1 “(i) a petition for an exemption for a
2 tobacco product from a requirement if the
3 Secretary determines that compliance with
4 such requirement is not required to assure
5 that the tobacco product will be in compli-
6 ance with this chapter; and

7 “(ii) a petition for a variance for a to-
8 bacco product from a requirement if the
9 Secretary determines that the methods to
10 be used in, and the facilities and controls
11 to be used for, the manufacture, packing,
12 and storage of the tobacco product in lieu
13 of the methods, facilities, and controls pre-
14 scribed by the requirement are sufficient to
15 assure that the tobacco product will be in
16 compliance with this chapter.

17 “(D) CONDITIONS.—An order of the Sec-
18 retary approving a petition for a variance shall
19 prescribe such conditions respecting the meth-
20 ods used in, and the facilities and controls used
21 for, the manufacture, packing, and storage of
22 the tobacco product to be granted the variance
23 under the petition as may be necessary to as-
24 sure that the tobacco product will be in compli-
25 ance with this chapter.

1 “(E) HEARING.—After the issuance of an
2 order under subparagraph (B) respecting a pe-
3 tition, the petitioner shall have an opportunity
4 for an informal hearing on such order.

5 “(3) COMPLIANCE.—Compliance with require-
6 ments under this subsection shall not be required be-
7 fore the end of the 3-year period following the date
8 of enactment of the Family Smoking Prevention and
9 Tobacco Control Act.

10 “(f) RESEARCH AND DEVELOPMENT.—The Secretary
11 may enter into contracts for research, testing, and dem-
12 onstrations respecting tobacco products and may obtain
13 tobacco products for research, testing, and demonstration
14 purposes.

15 **“SEC. 907. TOBACCO PRODUCT STANDARDS.**

16 “(a) IN GENERAL.—

17 “(1) SPECIAL RULES.—

18 “(A) SPECIAL RULE FOR CIGARETTES.—

19 Beginning 3 months after the date of enact-
20 ment of the Family Smoking Prevention and
21 Tobacco Control Act, a cigarette or any of its
22 component parts (including the tobacco, filter,
23 or paper) shall not contain, as a constituent (in-
24 cluding a smoke constituent) or additive, an ar-
25 tificial or natural flavor (other than tobacco or

1 menthol) or an herb or spice, including straw-
2 berry, grape, orange, clove, cinnamon, pine-
3 apple, vanilla, coconut, licorice, cocoa, chocolate,
4 cherry, or coffee, that is a characterizing flavor
5 of the tobacco product or tobacco smoke. Noth-
6 ing in this subparagraph shall be construed to
7 limit the Secretary's authority to take action
8 under this section or other sections of this Act
9 applicable to menthol or any artificial or nat-
10 ural flavor, herb, or spice not specified in this
11 subparagraph.

12 “(B) ADDITIONAL SPECIAL RULE.—Begin-
13 ning 2 years after the date of enactment of the
14 Family Smoking Prevention and Tobacco Con-
15 trol Act, a tobacco product manufacturer shall
16 not use tobacco, including foreign grown to-
17 bacco, that contains a pesticide chemical res-
18 idue that is at a level greater than is specified
19 by any tolerance applicable under Federal law
20 to domestically grown tobacco.

21 “(2) REVISION OF TOBACCO PRODUCT STAND-
22 ARDS.—The Secretary may revise the tobacco prod-
23 uct standards in paragraph (1) in accordance with
24 subsection (c).

25 “(3) TOBACCO PRODUCT STANDARDS.—

1 “(A) IN GENERAL.—The Secretary may
2 adopt tobacco product standards in addition to
3 those in paragraph (1) if the Secretary finds
4 that a tobacco product standard is appropriate
5 for the protection of the public health.

6 “(B) DETERMINATIONS.—

7 “(i) CONSIDERATIONS.—In making a
8 finding described in subparagraph (A), the
9 Secretary shall consider scientific evidence
10 concerning—

11 “(I) the risks and benefits to the
12 population as a whole, including users
13 and nonusers of tobacco products, of
14 the proposed standard;

15 “(II) the increased or decreased
16 likelihood that existing users of to-
17 bacco products will stop using such
18 products; and

19 “(III) the increased or decreased
20 likelihood that those who do not use
21 tobacco products will start using such
22 products.

23 “(ii) ADDITIONAL CONSIDER-
24 ATIONS.—In the event that the Secretary
25 makes a determination, set forth in a pro-

1 posed tobacco product standard in a pro-
2 posed rule, that it is appropriate for the
3 protection of public health to require the
4 reduction or elimination of an additive,
5 constituent (including a smoke con-
6 stituent), or other component of a tobacco
7 product because the Secretary has found
8 that the additive, constituent, or other
9 component is or may be harmful, any
10 party objecting to the proposed standard
11 on the ground that the proposed standard
12 will not reduce or eliminate the risk of ill-
13 ness or injury may provide for the Sec-
14 retary's consideration scientific evidence
15 that demonstrates that the proposed stand-
16 ard will not reduce or eliminate the risk of
17 illness or injury.

18 “(4) CONTENT OF TOBACCO PRODUCT STAND-
19 ARDS.—A tobacco product standard established
20 under this section for a tobacco product—

21 “(A) shall include provisions that are ap-
22 propriate for the protection of the public health,
23 including provisions, where appropriate—

24 “(i) for nicotine yields of the product;

1 “(ii) for the reduction or elimination
2 of other constituents, including smoke con-
3 stituents, or harmful components of the
4 product; or

5 “(iii) relating to any other require-
6 ment under subparagraph (B);

7 “(B) shall, where appropriate for the pro-
8 tection of the public health, include—

9 “(i) provisions respecting the con-
10 struction, components, ingredients, addi-
11 tives, constituents, including smoke con-
12 stituents, and properties of the tobacco
13 product;

14 “(ii) provisions for the testing (on a
15 sample basis or, if necessary, on an indi-
16 vidual basis) of the tobacco product;

17 “(iii) provisions for the measurement
18 of the tobacco product characteristics of
19 the tobacco product;

20 “(iv) provisions requiring that the re-
21 sults of each or of certain of the tests of
22 the tobacco product required to be made
23 under clause (ii) show that the tobacco
24 product is in conformity with the portions

1 of the standard for which the test or tests
2 were required; and

3 “(v) a provision requiring that the
4 sale and distribution of the tobacco prod-
5 uct be restricted but only to the extent
6 that the sale and distribution of a tobacco
7 product may be restricted under a regula-
8 tion under section 906(d);

9 “(C) shall, where appropriate, require the
10 use and prescribe the form and content of label-
11 ing for the proper use of the tobacco product;
12 and

13 “(D) shall require tobacco products con-
14 taining foreign-grown tobacco to meet the same
15 standards applicable to tobacco products con-
16 taining domestically grown tobacco.

17 “(5) PERIODIC REEVALUATION OF TOBACCO
18 PRODUCT STANDARDS.—The Secretary shall provide
19 for periodic evaluation of tobacco product standards
20 established under this section to determine whether
21 such standards should be changed to reflect new
22 medical, scientific, or other technological data. The
23 Secretary may provide for testing under paragraph
24 (4)(B) by any person.

1 “(6) INVOLVEMENT OF OTHER AGENCIES; IN-
2 FORMED PERSONS.—In carrying out duties under
3 this section, the Secretary shall endeavor to—

4 “(A) use personnel, facilities, and other
5 technical support available in other Federal
6 agencies;

7 “(B) consult with other Federal agencies
8 concerned with standard setting and other na-
9 tionally or internationally recognized standard-
10 setting entities; and

11 “(C) invite appropriate participation,
12 through joint or other conferences, workshops,
13 or other means, by informed persons represent-
14 ative of scientific, professional, industry, agri-
15 cultural, or consumer organizations who in the
16 Secretary’s judgment can make a significant
17 contribution.

18 “(b) CONSIDERATIONS BY SECRETARY.—

19 “(1) TECHNICAL ACHIEVABILITY.—The Sec-
20 retary shall consider information submitted in con-
21 nection with a proposed standard regarding the tech-
22 nical achievability of compliance with such standard.

23 “(2) OTHER CONSIDERATIONS.—The Secretary
24 shall consider all other information submitted in
25 connection with a proposed standard, including in-

1 formation concerning the countervailing effects of
2 the tobacco product standard on the health of ado-
3 lescent tobacco users, adult tobacco users, or non-
4 tobacco users, such as the creation of a significant
5 demand for contraband or other tobacco products
6 that do not meet the requirements of this chapter
7 and the significance of such demand.

8 “(c) PROPOSED STANDARDS.—

9 “(1) IN GENERAL.—The Secretary shall publish
10 in the Federal Register a notice of proposed rule-
11 making for the establishment, amendment, or rev-
12 ocation of any tobacco product standard.

13 “(2) REQUIREMENTS OF NOTICE.—A notice of
14 proposed rulemaking for the establishment or
15 amendment of a tobacco product standard for a to-
16 bacco product shall—

17 “(A) set forth a finding with supporting
18 justification that the tobacco product standard
19 is appropriate for the protection of the public
20 health;

21 “(B) invite interested persons to submit a
22 draft or proposed tobacco product standard for
23 consideration by the Secretary;

24 “(C) invite interested persons to submit
25 comments on structuring the standard so that

1 it does not advantage foreign-grown tobacco
2 over domestically grown tobacco; and

3 “(D) invite the Secretary of Agriculture to
4 provide any information or analysis which the
5 Secretary of Agriculture believes is relevant to
6 the proposed tobacco product standard.

7 “(3) FINDING.—A notice of proposed rule-
8 making for the revocation of a tobacco product
9 standard shall set forth a finding with supporting
10 justification that the tobacco product standard is no
11 longer appropriate for the protection of the public
12 health.

13 “(4) COMMENT.—The Secretary shall provide
14 for a comment period of not less than 60 days.

15 “(d) PROMULGATION.—

16 “(1) IN GENERAL.—After the expiration of the
17 period for comment on a notice of proposed rule-
18 making published under subsection (c) respecting a
19 tobacco product standard and after consideration of
20 comments submitted under subsections (b) and (c)
21 and any report from the Tobacco Products Scientific
22 Advisory Committee, the Secretary shall—

23 “(A) if the Secretary determines that the
24 standard would be appropriate for the protec-
25 tion of the public health, promulgate a regula-

1 tion establishing a tobacco product standard
2 and publish in the Federal Register findings on
3 the matters referred to in subsection (c); or

4 “(B) publish a notice terminating the pro-
5 ceeding for the development of the standard to-
6 gether with the reasons for such termination.

7 “(2) EFFECTIVE DATE.—A regulation estab-
8 lishing a tobacco product standard shall set forth
9 the date or dates upon which the standard shall take
10 effect, but no such regulation may take effect before
11 1 year after the date of its publication unless the
12 Secretary determines that an earlier effective date is
13 necessary for the protection of the public health.
14 Such date or dates shall be established so as to min-
15 imize, consistent with the public health, economic
16 loss to, and disruption or dislocation of, domestic
17 and international trade. In establishing such effec-
18 tive date or dates, the Secretary shall consider infor-
19 mation submitted in connection with a proposed
20 product standard by interested parties, including
21 manufacturers and tobacco growers, regarding the
22 technical achievability of compliance with the stand-
23 ard, and including information concerning the exist-
24 ence of patents that make it impossible to comply in
25 the timeframe envisioned in the proposed standard.

1 If the Secretary determines, based on the Sec-
2 retary's evaluation of submitted comments, that a
3 product standard can be met only by manufacturers
4 requiring substantial changes to the methods of
5 farming the domestically grown tobacco used by the
6 manufacturer, the effective date of that product
7 standard shall be not less than 2 years after the
8 date of publication of the final regulation estab-
9 lishing the standard.

10 “(3) LIMITATION ON POWER GRANTED TO THE
11 FOOD AND DRUG ADMINISTRATION.—Because of the
12 importance of a decision of the Secretary to issue a
13 regulation—

14 “(A) banning all cigarettes, all smokeless
15 tobacco products, all little cigars, all cigars
16 other than little cigars, all pipe tobacco, or all
17 roll-your-own tobacco products; or

18 “(B) requiring the reduction of nicotine
19 yields of a tobacco product to zero,
20 the Secretary is prohibited from taking such actions
21 under this Act.

22 “(4) AMENDMENT; REVOCATION.—

23 “(A) AUTHORITY.—The Secretary, upon
24 the Secretary's own initiative or upon petition
25 of an interested person, may by a regulation,

1 promulgated in accordance with the require-
2 ments of subsection (c) and paragraph (2),
3 amend or revoke a tobacco product standard.

4 “(B) EFFECTIVE DATE.—The Secretary
5 may declare a proposed amendment of a to-
6 bacco product standard to be effective on and
7 after its publication in the Federal Register and
8 until the effective date of any final action taken
9 on such amendment if the Secretary determines
10 that making it so effective is in the public inter-
11 est.

12 “(5) REFERRAL TO ADVISORY COMMITTEE.—

13 “(A) IN GENERAL.—The Secretary may
14 refer a proposed regulation for the establish-
15 ment, amendment, or revocation of a tobacco
16 product standard to the Tobacco Products Sci-
17 entific Advisory Committee for a report and
18 recommendation with respect to any matter in-
19 volved in the proposed regulation which requires
20 the exercise of scientific judgment.

21 “(B) INITIATION OF REFERRAL.—The Sec-
22 retary may make a referral under this para-
23 graph—

24 “(i) on the Secretary’s own initiative;
25 or

1 “(ii) upon the request of an interested
2 person that—

3 “(I) demonstrates good cause for
4 the referral; and

5 “(II) is made before the expira-
6 tion of the period for submission of
7 comments on the proposed regulation.

8 “(C) PROVISION OF DATA.—If a proposed
9 regulation is referred under this paragraph to
10 the Tobacco Products Scientific Advisory Com-
11 mittee, the Secretary shall provide the Advisory
12 Committee with the data and information on
13 which such proposed regulation is based.

14 “(D) REPORT AND RECOMMENDATION.—
15 The Tobacco Products Scientific Advisory Com-
16 mittee shall, within 60 days after the referral of
17 a proposed regulation under this paragraph and
18 after independent study of the data and infor-
19 mation furnished to it by the Secretary and
20 other data and information before it, submit to
21 the Secretary a report and recommendation re-
22 specting such regulation, together with all un-
23 derlying data and information and a statement
24 of the reason or basis for the recommendation.

1 “(E) PUBLIC AVAILABILITY.—The Sec-
2 retary shall make a copy of each report and rec-
3 ommendation under subparagraph (D) publicly
4 available.

5 “(e) MENTHOL CIGARETTES.—

6 “(1) REFERRAL; CONSIDERATIONS.—Imme-
7 diately upon the establishment of the Tobacco Prod-
8 ucts Scientific Advisory Committee under section
9 917(a), the Secretary shall refer to the Committee
10 for report and recommendation, under section
11 917(c)(4), the issue of the impact of the use of men-
12 thol in cigarettes on the public health, including
13 such use among African Americans, Hispanics, and
14 other racial and ethnic minorities. In its review, the
15 Tobacco Products Scientific Advisory Committee
16 shall address the considerations listed in subsections
17 (a)(3)(B)(i) and (b).

18 “(2) REPORT AND RECOMMENDATION.—Not
19 later than 1 year after its establishment, the To-
20 bacco Product Scientific Advisory Committee shall
21 submit to the Secretary the report and recommenda-
22 tions required pursuant to paragraph (1).

23 “(3) RULE OF CONSTRUCTION.—Nothing in
24 this subsection shall be construed to limit the Sec-

1 retary's authority to take action under this section
2 or other sections of this Act applicable to menthol.

3 **“SEC. 908. NOTIFICATION AND OTHER REMEDIES.**

4 “(a) NOTIFICATION.—If the Secretary determines
5 that—

6 “(1) a tobacco product which is introduced or
7 delivered for introduction into interstate commerce
8 for commercial distribution presents an unreasonable
9 risk of substantial harm to the public health; and

10 “(2) notification under this subsection is nec-
11 essary to eliminate the unreasonable risk of such
12 harm and no more practicable means is available
13 under the provisions of this chapter (other than this
14 section) to eliminate such risk,

15 the Secretary may issue such order as may be necessary
16 to assure that adequate notification is provided in an ap-
17 propriate form, by the persons and means best suited
18 under the circumstances involved, to all persons who
19 should properly receive such notification in order to elimi-
20 nate such risk. The Secretary may order notification by
21 any appropriate means, including public service announce-
22 ments. Before issuing an order under this subsection, the
23 Secretary shall consult with the persons who are to give
24 notice under the order.

1 “(b) NO EXEMPTION FROM OTHER LIABILITY.—

2 Compliance with an order issued under this section shall
3 not relieve any person from liability under Federal or
4 State law. In awarding damages for economic loss in an
5 action brought for the enforcement of any such liability,
6 the value to the plaintiff in such action of any remedy
7 provided under such order shall be taken into account.

8 “(c) RECALL AUTHORITY.—

9 “(1) IN GENERAL.—If the Secretary finds that
10 there is a reasonable probability that a tobacco prod-
11 uct contains a manufacturing or other defect not or-
12 dinarily contained in tobacco products on the market
13 that would cause serious, adverse health con-
14 sequences or death, the Secretary shall issue an
15 order requiring the appropriate person (including
16 the manufacturers, importers, distributors, or retail-
17 ers of the tobacco product) to immediately cease dis-
18 tribution of such tobacco product. The order shall
19 provide the person subject to the order with an op-
20 portunity for an informal hearing, to be held not
21 later than 10 days after the date of the issuance of
22 the order, on the actions required by the order and
23 on whether the order should be amended to require
24 a recall of such tobacco product. If, after providing
25 an opportunity for such a hearing, the Secretary de-

1 termines that inadequate grounds exist to support
2 the actions required by the order, the Secretary shall
3 vacate the order.

4 “(2) AMENDMENT OF ORDER TO REQUIRE RE-
5 CALL.—

6 “(A) IN GENERAL.—If, after providing an
7 opportunity for an informal hearing under
8 paragraph (1), the Secretary determines that
9 the order should be amended to include a recall
10 of the tobacco product with respect to which the
11 order was issued, the Secretary shall, except as
12 provided in subparagraph (B), amend the order
13 to require a recall. The Secretary shall specify
14 a timetable in which the tobacco product recall
15 will occur and shall require periodic reports to
16 the Secretary describing the progress of the re-
17 call.

18 “(B) NOTICE.—An amended order under
19 subparagraph (A)—

20 “(i) shall not include recall of a to-
21 bacco product from individuals; and

22 “(ii) shall provide for notice to per-
23 sons subject to the risks associated with
24 the use of such tobacco product.

1 In providing the notice required by clause (ii),
2 the Secretary may use the assistance of retail-
3 ers and other persons who distributed such to-
4 bacco product. If a significant number of such
5 persons cannot be identified, the Secretary shall
6 notify such persons under section 705(b).

7 “(3) REMEDY NOT EXCLUSIVE.—The remedy
8 provided by this subsection shall be in addition to
9 remedies provided by subsection (a).

10 **“SEC. 909. RECORDS AND REPORTS ON TOBACCO PROD-**
11 **UCTS.**

12 “(a) IN GENERAL.—Every person who is a tobacco
13 product manufacturer or importer of a tobacco product
14 shall establish and maintain such records, make such re-
15 ports, and provide such information, as the Secretary may
16 by regulation reasonably require to assure that such to-
17 bacco product is not adulterated or misbranded and to
18 otherwise protect public health. Regulations prescribed
19 under the preceding sentence—

20 “(1) may require a tobacco product manufac-
21 turer or importer to report to the Secretary when-
22 ever the manufacturer or importer receives or other-
23 wise becomes aware of information that reasonably
24 suggests that one of its marketed tobacco products
25 may have caused or contributed to a serious unex-

1 pected adverse experience associated with the use of
2 the product or any significant increase in the fre-
3 quency of a serious, expected adverse product experi-
4 ence;

5 “(2) shall require reporting of other significant
6 adverse tobacco product experiences as determined
7 by the Secretary to be necessary to be reported;

8 “(3) shall not impose requirements unduly bur-
9 densome to a tobacco product manufacturer or im-
10 porter, taking into account the cost of complying
11 with such requirements and the need for the protec-
12 tion of the public health and the implementation of
13 this chapter;

14 “(4) when prescribing the procedure for making
15 requests for reports or information, shall require
16 that each request made under such regulations for
17 submission of a report or information to the Sec-
18 retary state the reason or purpose for such request
19 and identify to the fullest extent practicable such re-
20 port or information;

21 “(5) when requiring submission of a report or
22 information to the Secretary, shall state the reason
23 or purpose for the submission of such report or in-
24 formation and identify to the fullest extent prac-
25 ticable such report or information; and

1 “(6) may not require that the identity of any
2 patient or user be disclosed in records, reports, or
3 information required under this subsection unless re-
4 quired for the medical welfare of an individual, to
5 determine risks to public health of a tobacco prod-
6 uct, or to verify a record, report, or information sub-
7 mitted under this chapter.

8 In prescribing regulations under this subsection, the Sec-
9 retary shall have due regard for the professional ethics of
10 the medical profession and the interests of patients. The
11 prohibitions of paragraph (6) continue to apply to records,
12 reports, and information concerning any individual who
13 has been a patient, irrespective of whether or when he
14 ceases to be a patient.

15 “(b) REPORTS OF REMOVALS AND CORRECTIONS.—

16 “(1) IN GENERAL.—Except as provided in para-
17 graph (2), the Secretary shall by regulation require
18 a tobacco product manufacturer or importer of a to-
19 bacco product to report promptly to the Secretary
20 any corrective action taken or removal from the
21 market of a tobacco product undertaken by such
22 manufacturer or importer if the removal or correc-
23 tion was undertaken—

24 “(A) to reduce a risk to health posed by
25 the tobacco product; or

1 “(B) to remedy a violation of this chapter
2 caused by the tobacco product which may
3 present a risk to health.

4 A tobacco product manufacturer or importer of a to-
5 bacco product who undertakes a corrective action or
6 removal from the market of a tobacco product which
7 is not required to be reported under this subsection
8 shall keep a record of such correction or removal.

9 “(2) EXCEPTION.—No report of the corrective
10 action or removal of a tobacco product may be re-
11 quired under paragraph (1) if a report of the correc-
12 tive action or removal is required and has been sub-
13 mitted under subsection (a).

14 **“SEC. 910. APPLICATION FOR REVIEW OF CERTAIN TO-**
15 **BACCO PRODUCTS.**

16 “(a) IN GENERAL.—

17 “(1) NEW TOBACCO PRODUCT DEFINED.—For
18 purposes of this section the term ‘new tobacco prod-
19 uct’ means—

20 “(A) any tobacco product (including those
21 products in test markets) that was not commer-
22 cially marketed in the United States as of Feb-
23 ruary 15, 2007; or

24 “(B) any modification (including a change
25 in design, any component, any part, or any con-

1 stituent, including a smoke constituent, or in
2 the content, delivery or form of nicotine, or any
3 other additive or ingredient) of a tobacco prod-
4 uct where the modified product was commer-
5 cially marketed in the United States after Feb-
6 ruary 15, 2007.

7 “(2) PREMARKET REVIEW REQUIRED.—

8 “(A) NEW PRODUCTS.—An order under
9 subsection (c)(1)(A)(i) for a new tobacco prod-
10 uct is required unless—

11 “(i) the manufacturer has submitted a
12 report under section 905(j); and the Sec-
13 retary has issued an order that the tobacco
14 product—

15 “(I) is substantially equivalent to
16 a tobacco product commercially mar-
17 keted (other than for test marketing)
18 in the United States as of February
19 15, 2007; and

20 “(II) is in compliance with the
21 requirements of this Act; or

22 “(ii) the tobacco product is exempt
23 from the requirements of section 905(j)
24 pursuant to a regulation issued under sec-
25 tion 905(j)(3).

1 “(B) APPLICATION TO CERTAIN POST-FEB-
2 RUARY 15, 2007, PRODUCTS.—Subparagraph (A)
3 shall not apply to a tobacco product—

4 “(i) that was first introduced or deliv-
5 ered for introduction into interstate com-
6 merce for commercial distribution in the
7 United States after February 15, 2007,
8 and prior to the date that is 21 months
9 after the date of enactment of the Family
10 Smoking Prevention and Tobacco Control
11 Act; and

12 “(ii) for which a report was submitted
13 under section 905(j) within such 21-month
14 period,

15 except that subparagraph (A) shall apply to the
16 tobacco product if the Secretary issues an order
17 that the tobacco product is not substantially
18 equivalent.

19 “(3) SUBSTANTIALLY EQUIVALENT DEFINED.—

20 “(A) IN GENERAL.—In this section and
21 section 905(j), the term ‘substantially equiva-
22 lent’ or ‘substantial equivalence’ means, with
23 respect to the tobacco product being compared
24 to the predicate tobacco product, that the Sec-

1 retary by order has found that the tobacco
2 product—

3 “(i) has the same characteristics as
4 the predicate tobacco product; or

5 “(ii) has different characteristics and
6 the information submitted contains infor-
7 mation, including clinical data if deemed
8 necessary by the Secretary, that dem-
9 onstrates that it is not appropriate to reg-
10 ulate the product under this section be-
11 cause the product does not raise different
12 questions of public health.

13 “(B) CHARACTERISTICS.—In subpara-
14 graph (A), the term ‘characteristics’ means the
15 materials, ingredients, design, composition,
16 heating source, or other features of a tobacco
17 product.

18 “(C) LIMITATION.—A tobacco product may
19 not be found to be substantially equivalent to a
20 predicate tobacco product that has been re-
21 moved from the market at the initiative of the
22 Secretary or that has been determined by a ju-
23 dicial order to be misbranded or adulterated.

24 “(4) HEALTH INFORMATION.—

1 “(A) SUMMARY.—As part of a submission
2 under section 905(j) respecting a tobacco prod-
3 uct, the person required to file a premarket no-
4 tification under such section shall provide an
5 adequate summary of any health information
6 related to the tobacco product or state that
7 such information will be made available upon
8 request by any person.

9 “(B) REQUIRED INFORMATION.—Any sum-
10 mary under subparagraph (A) respecting a to-
11 bacco product shall contain detailed information
12 regarding data concerning adverse health ef-
13 fects and shall be made available to the public
14 by the Secretary within 30 days of the issuance
15 of a determination that such tobacco product is
16 substantially equivalent to another tobacco
17 product.

18 “(b) APPLICATION.—

19 “(1) CONTENTS.—An application under this
20 section shall contain—

21 “(A) full reports of all information, pub-
22 lished or known to, or which should reasonably
23 be known to, the applicant, concerning inves-
24 tigations which have been made to show the
25 health risks of such tobacco product and wheth-

1 er such tobacco product presents less risk than
2 other tobacco products;

3 “(B) a full statement of the components,
4 ingredients, additives, and properties, and of
5 the principle or principles of operation, of such
6 tobacco product;

7 “(C) a full description of the methods used
8 in, and the facilities and controls used for, the
9 manufacture, processing, and, when relevant,
10 packing and installation of, such tobacco prod-
11 uct;

12 “(D) an identifying reference to any to-
13 bacco product standard under section 907
14 which would be applicable to any aspect of such
15 tobacco product, and either adequate informa-
16 tion to show that such aspect of such tobacco
17 product fully meets such tobacco product stand-
18 ard or adequate information to justify any devi-
19 ation from such standard;

20 “(E) such samples of such tobacco product
21 and of components thereof as the Secretary
22 may reasonably require;

23 “(F) specimens of the labeling proposed to
24 be used for such tobacco product; and

1 “(G) such other information relevant to
2 the subject matter of the application as the Sec-
3 retary may require.

4 “(2) REFERRAL TO TOBACCO PRODUCTS SCI-
5 ENTIFIC ADVISORY COMMITTEE.—Upon receipt of an
6 application meeting the requirements set forth in
7 paragraph (1), the Secretary—

8 “(A) may, on the Secretary’s own initia-
9 tive; or

10 “(B) may, upon the request of an appli-
11 cant,

12 refer such application to the Tobacco Products Sci-
13 entific Advisory Committee for reference and for
14 submission (within such period as the Secretary may
15 establish) of a report and recommendation respect-
16 ing the application, together with all underlying data
17 and the reasons or basis for the recommendation.

18 “(c) ACTION ON APPLICATION.—

19 “(1) DEADLINE.—

20 “(A) IN GENERAL.—As promptly as pos-
21 sible, but in no event later than 180 days after
22 the receipt of an application under subsection
23 (b), the Secretary, after considering the report
24 and recommendation submitted under sub-
25 section (b)(2), shall—

1 “(i) issue an order that the new prod-
2 uct may be introduced or delivered for in-
3 troduction into interstate commerce if the
4 Secretary finds that none of the grounds
5 specified in paragraph (2) of this sub-
6 section applies; or

7 “(ii) issue an order that the new prod-
8 uct may not be introduced or delivered for
9 introduction into interstate commerce if
10 the Secretary finds (and sets forth the
11 basis for such finding as part of or accom-
12 panying such denial) that 1 or more
13 grounds for denial specified in paragraph
14 (2) of this subsection apply.

15 “(B) RESTRICTIONS ON SALE AND DIS-
16 TRIBUTION.—An order under subparagraph
17 (A)(i) may require that the sale and distribu-
18 tion of the tobacco product be restricted but
19 only to the extent that the sale and distribution
20 of a tobacco product may be restricted under a
21 regulation under section 906(d).

22 “(2) DENIAL OF APPLICATION.—The Secretary
23 shall deny an application submitted under subsection
24 (b) if, upon the basis of the information submitted
25 to the Secretary as part of the application and any

1 other information before the Secretary with respect
2 to such tobacco product, the Secretary finds that—

3 “(A) there is a lack of a showing that per-
4 mitting such tobacco product to be marketed
5 would be appropriate for the protection of the
6 public health;

7 “(B) the methods used in, or the facilities
8 or controls used for, the manufacture, proc-
9 essing, or packing of such tobacco product do
10 not conform to the requirements of section
11 906(e);

12 “(C) based on a fair evaluation of all mate-
13 rial facts, the proposed labeling is false or mis-
14 leading in any particular; or

15 “(D) such tobacco product is not shown to
16 conform in all respects to a tobacco product
17 standard in effect under section 907, and there
18 is a lack of adequate information to justify the
19 deviation from such standard.

20 “(3) DENIAL INFORMATION.—Any denial of an
21 application shall, insofar as the Secretary determines
22 to be practicable, be accompanied by a statement in-
23 forming the applicant of the measures required to
24 remove such application from deniable form (which
25 measures may include further research by the appli-

1 cant in accordance with 1 or more protocols pre-
2 scribed by the Secretary).

3 “(4) BASIS FOR FINDING.—For purposes of
4 this section, the finding as to whether the marketing
5 of a tobacco product for which an application has
6 been submitted is appropriate for the protection of
7 the public health shall be determined with respect to
8 the risks and benefits to the population as a whole,
9 including users and nonusers of the tobacco product,
10 and taking into account—

11 “(A) the increased or decreased likelihood
12 that existing users of tobacco products will stop
13 using such products; and

14 “(B) the increased or decreased likelihood
15 that those who do not use tobacco products will
16 start using such products.

17 “(5) BASIS FOR ACTION.—

18 “(A) INVESTIGATIONS.—For purposes of
19 paragraph (2)(A), whether permitting a tobacco
20 product to be marketed would be appropriate
21 for the protection of the public health shall,
22 when appropriate, be determined on the basis of
23 well-controlled investigations, which may in-
24 clude 1 or more clinical investigations by ex-

1 perts qualified by training and experience to
2 evaluate the tobacco product.

3 “(B) OTHER EVIDENCE.—If the Secretary
4 determines that there exists valid scientific evi-
5 dence (other than evidence derived from inves-
6 tigations described in subparagraph (A)) which
7 is sufficient to evaluate the tobacco product, the
8 Secretary may authorize that the determination
9 for purposes of paragraph (2)(A) be made on
10 the basis of such evidence.

11 “(d) WITHDRAWAL AND TEMPORARY SUSPENSION.—

12 “(1) IN GENERAL.—The Secretary shall, upon
13 obtaining, where appropriate, advice on scientific
14 matters from the Tobacco Products Scientific Advi-
15 sory Committee, and after due notice and oppor-
16 tunity for informal hearing for a tobacco product for
17 which an order was issued under subsection
18 (c)(1)(A)(i), issue an order withdrawing the order if
19 the Secretary finds—

20 “(A) that the continued marketing of such
21 tobacco product no longer is appropriate for the
22 protection of the public health;

23 “(B) that the application contained or was
24 accompanied by an untrue statement of a mate-
25 rial fact;

1 “(C) that the applicant—

2 “(i) has failed to establish a system
3 for maintaining records, or has repeatedly
4 or deliberately failed to maintain records
5 or to make reports, required by an applica-
6 ble regulation under section 909;

7 “(ii) has refused to permit access to,
8 or copying or verification of, such records
9 as required by section 704; or

10 “(iii) has not complied with the re-
11 quirements of section 905;

12 “(D) on the basis of new information be-
13 fore the Secretary with respect to such tobacco
14 product, evaluated together with the evidence
15 before the Secretary when the application was
16 reviewed, that the methods used in, or the fa-
17 cilities and controls used for, the manufacture,
18 processing, packing, or installation of such to-
19 bacco product do not conform with the require-
20 ments of section 906(e) and were not brought
21 into conformity with such requirements within a
22 reasonable time after receipt of written notice
23 from the Secretary of nonconformity;

24 “(E) on the basis of new information be-
25 fore the Secretary, evaluated together with the

1 evidence before the Secretary when the applica-
2 tion was reviewed, that the labeling of such to-
3 bacco product, based on a fair evaluation of all
4 material facts, is false or misleading in any par-
5 ticular and was not corrected within a reason-
6 able time after receipt of written notice from
7 the Secretary of such fact; or

8 “(F) on the basis of new information be-
9 fore the Secretary, evaluated together with the
10 evidence before the Secretary when such order
11 was issued, that such tobacco product is not
12 shown to conform in all respects to a tobacco
13 product standard which is in effect under sec-
14 tion 907, compliance with which was a condi-
15 tion to the issuance of an order relating to the
16 application, and that there is a lack of adequate
17 information to justify the deviation from such
18 standard.

19 “(2) APPEAL.—The holder of an application
20 subject to an order issued under paragraph (1) with-
21 drawing an order issued pursuant to subsection
22 (c)(1)(A)(i) may, by petition filed on or before the
23 30th day after the date upon which such holder re-
24 ceives notice of such withdrawal, obtain review there-
25 of in accordance with section 912.

1 “(3) TEMPORARY SUSPENSION.—If, after pro-
2 viding an opportunity for an informal hearing, the
3 Secretary determines there is reasonable probability
4 that the continuation of distribution of a tobacco
5 product under an order would cause serious, adverse
6 health consequences or death, that is greater than
7 ordinarily caused by tobacco products on the market,
8 the Secretary shall by order temporarily suspend the
9 authority of the manufacturer to market the prod-
10 uct. If the Secretary issues such an order, the Sec-
11 retary shall proceed expeditiously under paragraph
12 (1) to withdraw such application.

13 “(e) SERVICE OF ORDER.—An order issued by the
14 Secretary under this section shall be served—

15 “(1) in person by any officer or employee of the
16 department designated by the Secretary; or

17 “(2) by mailing the order by registered mail or
18 certified mail addressed to the applicant at the ap-
19 plicant’s last known address in the records of the
20 Secretary.

21 “(f) RECORDS.—

22 “(1) ADDITIONAL INFORMATION.—In the case
23 of any tobacco product for which an order issued
24 pursuant to subsection (c)(1)(A)(i) for an applica-
25 tion filed under subsection (b) is in effect, the appli-

1 cant shall establish and maintain such records, and
2 make such reports to the Secretary, as the Secretary
3 may by regulation, or by order with respect to such
4 application, prescribe on the basis of a finding that
5 such records and reports are necessary in order to
6 enable the Secretary to determine, or facilitate a de-
7 termination of, whether there is or may be grounds
8 for withdrawing or temporarily suspending such
9 order.

10 “(2) ACCESS TO RECORDS.—Each person re-
11 quired under this section to maintain records, and
12 each person in charge of custody thereof, shall, upon
13 request of an officer or employee designated by the
14 Secretary, permit such officer or employee at all rea-
15 sonable times to have access to and copy and verify
16 such records.

17 “(g) INVESTIGATIONAL TOBACCO PRODUCT EXEMP-
18 TION FOR INVESTIGATIONAL USE.—The Secretary may
19 exempt tobacco products intended for investigational use
20 from the provisions of this chapter under such conditions
21 as the Secretary may by regulation prescribe.

22 **“SEC. 911. MODIFIED RISK TOBACCO PRODUCTS.**

23 “(a) IN GENERAL.—No person may introduce or de-
24 liver for introduction into interstate commerce any modi-

1 fied risk tobacco product unless an order issued pursuant
2 to subsection (g) is effective with respect to such product.

3 “(b) DEFINITIONS.—In this section:

4 “(1) MODIFIED RISK TOBACCO PRODUCT.—The
5 term ‘modified risk tobacco product’ means any to-
6 bacco product that is sold or distributed for use to
7 reduce harm or the risk of tobacco-related disease
8 associated with commercially marketed tobacco prod-
9 ucts.

10 “(2) SOLD OR DISTRIBUTED.—

11 “(A) IN GENERAL.—With respect to a to-
12 bacco product, the term ‘sold or distributed for
13 use to reduce harm or the risk of tobacco-re-
14 lated disease associated with commercially mar-
15 keted tobacco products’ means a tobacco prod-
16 uct—

17 “(i) the label, labeling, or advertising
18 of which represents explicitly or implicitly
19 that—

20 “(I) the tobacco product presents
21 a lower risk of tobacco-related disease
22 or is less harmful than one or more
23 other commercially marketed tobacco
24 products;

1 “(II) the tobacco product or its
2 smoke contains a reduced level of a
3 substance or presents a reduced expo-
4 sure to a substance; or

5 “(III) the tobacco product or its
6 smoke does not contain or is free of a
7 substance;

8 “(ii) the label, labeling, or advertising
9 of which uses the descriptors ‘light’, ‘mild’,
10 or ‘low’ or similar descriptors; or

11 “(iii) the tobacco product manufac-
12 turer of which has taken any action di-
13 rected to consumers through the media or
14 otherwise, other than by means of the to-
15 bacco product’s label, labeling, or adver-
16 tising, after the date of enactment of the
17 Family Smoking Prevention and Tobacco
18 Control Act, respecting the product that
19 would be reasonably expected to result in
20 consumers believing that the tobacco prod-
21 uct or its smoke may present a lower risk
22 of disease or is less harmful than one or
23 more commercially marketed tobacco prod-
24 ucts, or presents a reduced exposure to, or

1 does not contain or is free of, a substance
2 or substances.

3 “(B) LIMITATION.—No tobacco product
4 shall be considered to be ‘sold or distributed for
5 use to reduce harm or the risk of tobacco-re-
6 lated disease associated with commercially mar-
7 keted tobacco products’, except as described in
8 subparagraph (A).

9 “(C) SMOKELESS TOBACCO PRODUCT.—No
10 smokeless tobacco product shall be considered
11 to be ‘sold or distributed for use to reduce harm
12 or the risk of tobacco-related disease associated
13 with commercially marketed tobacco products’
14 solely because its label, labeling, or advertising
15 uses the following phrases to describe such
16 product and its use: ‘smokeless tobacco’,
17 ‘smokeless tobacco product’, ‘not consumed by
18 smoking’, ‘does not produce smoke’,
19 ‘smokefree’, ‘smoke-free’, ‘without smoke’, ‘no
20 smoke’, or ‘not smoke’.

21 “(3) EFFECTIVE DATE.—The provisions of
22 paragraph (2)(A)(ii) shall take effect 12 months
23 after the date of enactment of the Family Smoking
24 Prevention and Tobacco Control Act for those prod-
25 ucts whose label, labeling, or advertising contains

1 the terms described in such paragraph on such date
2 of enactment. The effective date shall be with re-
3 spect to the date of manufacture, provided that, in
4 any case, beginning 30 days after such effective
5 date, a manufacturer shall not introduce into the do-
6 mestic commerce of the United States any product,
7 irrespective of the date of manufacture, that is not
8 in conformance with paragraph (2)(A)(ii).

9 “(c) TOBACCO DEPENDENCE PRODUCTS.—A product
10 that is intended to be used for the treatment of tobacco
11 dependence, including smoking cessation, is not a modified
12 risk tobacco product under this section if it has been ap-
13 proved as a drug or device by the Food and Drug Adminis-
14 tration and is subject to the requirements of chapter V.

15 “(d) FILING.—Any person may file with the Sec-
16 retary an application for a modified risk tobacco product.
17 Such application shall include—

18 “(1) a description of the proposed product and
19 any proposed advertising and labeling;

20 “(2) the conditions for using the product;

21 “(3) the formulation of the product;

22 “(4) sample product labels and labeling;

23 “(5) all documents (including underlying sci-
24 entific information) relating to research findings
25 conducted, supported, or possessed by the tobacco

1 product manufacturer relating to the effect of the
2 product on tobacco-related diseases and health-re-
3 lated conditions, including information both favor-
4 able and unfavorable to the ability of the product to
5 reduce risk or exposure and relating to human
6 health;

7 “(6) data and information on how consumers
8 actually use the tobacco product; and

9 “(7) such other information as the Secretary
10 may require.

11 “(e) PUBLIC AVAILABILITY.—The Secretary shall
12 make the application described in subsection (d) publicly
13 available (except matters in the application which are
14 trade secrets or otherwise confidential, commercial infor-
15 mation) and shall request comments by interested persons
16 on the information contained in the application and on the
17 label, labeling, and advertising accompanying such appli-
18 cation.

19 “(f) ADVISORY COMMITTEE.—

20 “(1) IN GENERAL.—The Secretary shall refer to
21 the Tobacco Products Scientific Advisory Committee
22 any application submitted under this section.

23 “(2) RECOMMENDATIONS.—Not later than 60
24 days after the date an application is referred to the
25 Tobacco Products Scientific Advisory Committee

1 under paragraph (1), the Advisory Committee shall
2 report its recommendations on the application to the
3 Secretary.

4 “(g) MARKETING.—

5 “(1) MODIFIED RISK PRODUCTS.—Except as
6 provided in paragraph (2), the Secretary shall, with
7 respect to an application submitted under this sec-
8 tion, issue an order that a modified risk product
9 may be commercially marketed only if the Secretary
10 determines that the applicant has demonstrated that
11 such product, as it is actually used by consumers,
12 will—

13 “(A) significantly reduce harm and the
14 risk of tobacco-related disease to individual to-
15 bacco users; and

16 “(B) benefit the health of the population
17 as a whole taking into account both users of to-
18 bacco products and persons who do not cur-
19 rently use tobacco products.

20 “(2) SPECIAL RULE FOR CERTAIN PRODUCTS.—

21 “(A) IN GENERAL.—The Secretary may
22 issue an order that a tobacco product may be
23 introduced or delivered for introduction into
24 interstate commerce, pursuant to an application
25 under this section, with respect to a tobacco

1 product that may not be commercially marketed
2 under paragraph (1) if the Secretary makes the
3 findings required under this paragraph and de-
4 termines that the applicant has demonstrated
5 that—

6 “(i) such order would be appropriate
7 to promote the public health;

8 “(ii) any aspect of the label, labeling,
9 and advertising for such product that
10 would cause the tobacco product to be a
11 modified risk tobacco product under sub-
12 section (b) is limited to an explicit or im-
13 plicit representation that such tobacco
14 product or its smoke does not contain or is
15 free of a substance or contains a reduced
16 level of a substance, or presents a reduced
17 exposure to a substance in tobacco smoke;

18 “(iii) scientific evidence is not avail-
19 able and, using the best available scientific
20 methods, cannot be made available without
21 conducting long-term epidemiological stud-
22 ies for an application to meet the stand-
23 ards set forth in paragraph (1); and

24 “(iv) the scientific evidence that is
25 available without conducting long-term epi-

1 demiological studies demonstrates that a
2 measurable and substantial reduction in
3 morbidity or mortality among individual
4 tobacco users is reasonably likely in subse-
5 quent studies.

6 “(B) ADDITIONAL FINDINGS REQUIRED.—
7 To issue an order under subparagraph (A) the
8 Secretary must also find that the applicant has
9 demonstrated that—

10 “(i) the magnitude of the overall re-
11 ductions in exposure to the substance or
12 substances which are the subject of the ap-
13 plication is substantial, such substance or
14 substances are harmful, and the product as
15 actually used exposes consumers to the
16 specified reduced level of the substance or
17 substances;

18 “(ii) the product as actually used by
19 consumers will not expose them to higher
20 levels of other harmful substances com-
21 pared to the similar types of tobacco prod-
22 ucts then on the market unless such in-
23 creases are minimal and the reasonably
24 likely overall impact of use of the product
25 remains a substantial and measurable re-

1 duction in overall morbidity and mortality
2 among individual tobacco users;

3 “(iii) testing of actual consumer per-
4 ception shows that, as the applicant pro-
5 poses to label and market the product, con-
6 sumers will not be misled into believing
7 that the product—

8 “(I) is or has been demonstrated
9 to be less harmful; or

10 “(II) presents or has been dem-
11 onstrated to present less of a risk of
12 disease than 1 or more other commer-
13 cially marketed tobacco products; and

14 “(iv) issuance of an order with respect
15 to the application is expected to benefit the
16 health of the population as a whole taking
17 into account both users of tobacco prod-
18 ucts and persons who do not currently use
19 tobacco products.

20 “(C) CONDITIONS OF MARKETING.—

21 “(i) IN GENERAL.—Applications sub-
22 ject to an order under this paragraph shall
23 be limited to a term of not more than 5
24 years, but may be renewed upon a finding
25 by the Secretary that the requirements of

1 this paragraph continue to be satisfied
2 based on the filing of a new application.

3 “(ii) AGREEMENTS BY APPLICANT.—

4 An order under this paragraph shall be
5 conditioned on the applicant’s agreement
6 to conduct postmarket surveillance and
7 studies and to submit to the Secretary the
8 results of such surveillance and studies to
9 determine the impact of the order on con-
10 sumer perception, behavior, and health and
11 to enable the Secretary to review the accu-
12 racy of the determinations upon which the
13 order was based in accordance with a pro-
14 tocol approved by the Secretary.

15 “(iii) ANNUAL SUBMISSION.—The re-
16 sults of such postmarket surveillance and
17 studies described in clause (ii) shall be
18 submitted annually.

19 “(3) BASIS.—The determinations under para-
20 graphs (1) and (2) shall be based on—

21 “(A) the scientific evidence submitted by
22 the applicant; and

23 “(B) scientific evidence and other informa-
24 tion that is made available to the Secretary.

1 “(4) BENEFIT TO HEALTH OF INDIVIDUALS
2 AND OF POPULATION AS A WHOLE.—In making the
3 determinations under paragraphs (1) and (2), the
4 Secretary shall take into account—

5 “(A) the relative health risks to individuals
6 of the tobacco product that is the subject of the
7 application;

8 “(B) the increased or decreased likelihood
9 that existing users of tobacco products who
10 would otherwise stop using such products will
11 switch to the tobacco product that is the subject
12 of the application;

13 “(C) the increased or decreased likelihood
14 that persons who do not use tobacco products
15 will start using the tobacco product that is the
16 subject of the application;

17 “(D) the risks and benefits to persons
18 from the use of the tobacco product that is the
19 subject of the application as compared to the
20 use of products for smoking cessation approved
21 under chapter V to treat nicotine dependence;
22 and

23 “(E) comments, data, and information
24 submitted by interested persons.

25 “(h) ADDITIONAL CONDITIONS FOR MARKETING.—

1 “(1) MODIFIED RISK PRODUCTS.—The Sec-
2 retary shall require for the marketing of a product
3 under this section that any advertising or labeling
4 concerning modified risk products enable the public
5 to comprehend the information concerning modified
6 risk and to understand the relative significance of
7 such information in the context of total health and
8 in relation to all of the diseases and health-related
9 conditions associated with the use of tobacco prod-
10 ucts.

11 “(2) COMPARATIVE CLAIMS.—

12 “(A) IN GENERAL.—The Secretary may re-
13 quire for the marketing of a product under this
14 subsection that a claim comparing a tobacco
15 product to 1 or more other commercially mar-
16 keted tobacco products shall compare the to-
17 bacco product to a commercially marketed to-
18 bacco product that is representative of that type
19 of tobacco product on the market (for example
20 the average value of the top 3 brands of an es-
21 tablished regular tobacco product).

22 “(B) QUANTITATIVE COMPARISONS.—The
23 Secretary may also require, for purposes of sub-
24 paragraph (A), that the percent (or fraction) of
25 change and identity of the reference tobacco

1 product and a quantitative comparison of the
2 amount of the substance claimed to be reduced
3 shall be stated in immediate proximity to the
4 most prominent claim.

5 “(3) LABEL DISCLOSURE.—

6 “(A) IN GENERAL.—The Secretary may re-
7 quire the disclosure on the label of other sub-
8 stances in the tobacco product, or substances
9 that may be produced by the consumption of
10 that tobacco product, that may affect a disease
11 or health-related condition or may increase the
12 risk of other diseases or health-related condi-
13 tions associated with the use of tobacco prod-
14 ucts.

15 “(B) CONDITIONS OF USE.—If the condi-
16 tions of use of the tobacco product may affect
17 the risk of the product to human health, the
18 Secretary may require the labeling of conditions
19 of use.

20 “(4) TIME.—An order issued under subsection
21 (g)(1) shall be effective for a specified period of
22 time.

23 “(5) ADVERTISING.—The Secretary may re-
24 quire, with respect to a product for which an appli-
25 cant obtained an order under subsection (g)(1), that

1 the product comply with requirements relating to ad-
2 vertising and promotion of the tobacco product.

3 “(i) POSTMARKET SURVEILLANCE AND STUDIES.—

4 “(1) IN GENERAL.—The Secretary shall re-
5 quire, with respect to a product for which an appli-
6 cant obtained an order under subsection (g)(1), that
7 the applicant conduct postmarket surveillance and
8 studies for such a tobacco product to determine the
9 impact of the order issuance on consumer percep-
10 tion, behavior, and health, to enable the Secretary to
11 review the accuracy of the determinations upon
12 which the order was based, and to provide informa-
13 tion that the Secretary determines is otherwise nec-
14 essary regarding the use or health risks involving
15 the tobacco product. The results of postmarket sur-
16 veillance and studies shall be submitted to the Sec-
17 retary on an annual basis.

18 “(2) SURVEILLANCE PROTOCOL.—Each appli-
19 cant required to conduct a surveillance of a tobacco
20 product under paragraph (1) shall, within 30 days
21 after receiving notice that the applicant is required
22 to conduct such surveillance, submit, for the ap-
23 proval of the Secretary, a protocol for the required
24 surveillance. The Secretary, within 60 days of the
25 receipt of such protocol, shall determine if the prin-

1 cipal investigator proposed to be used in the surveil-
2 lance has sufficient qualifications and experience to
3 conduct such surveillance and if such protocol will
4 result in collection of the data or other information
5 designated by the Secretary as necessary to protect
6 the public health.

7 “(j) WITHDRAWAL OF AUTHORIZATION.—The Sec-
8 retary, after an opportunity for an informal hearing, shall
9 withdraw an order under subsection (g) if the Secretary
10 determines that—

11 “(1) the applicant, based on new information,
12 can no longer make the demonstrations required
13 under subsection (g), or the Secretary can no longer
14 make the determinations required under subsection
15 (g);

16 “(2) the application failed to include material
17 information or included any untrue statement of ma-
18 terial fact;

19 “(3) any explicit or implicit representation that
20 the product reduces risk or exposure is no longer
21 valid, including if—

22 “(A) a tobacco product standard is estab-
23 lished pursuant to section 907;

24 “(B) an action is taken that affects the
25 risks presented by other commercially marketed

1 tobacco products that were compared to the
2 product that is the subject of the application; or

3 “(C) any postmarket surveillance or stud-
4 ies reveal that the order is no longer consistent
5 with the protection of the public health;

6 “(4) the applicant failed to conduct or submit
7 the postmarket surveillance and studies required
8 under subsection (g)(2)(C)(ii) or subsection (i); or

9 “(5) the applicant failed to meet a condition
10 imposed under subsection (h).

11 “(k) CHAPTER IV OR V.—A product for which the
12 Secretary has issued an order pursuant to subsection (g)
13 shall not be subject to chapter IV or V.

14 “(l) IMPLEMENTING REGULATIONS OR GUIDANCE.—

15 “(1) SCIENTIFIC EVIDENCE.—Not later than 2
16 years after the date of enactment of the Family
17 Smoking Prevention and Tobacco Control Act, the
18 Secretary shall issue regulations or guidance (or any
19 combination thereof) on the scientific evidence re-
20 quired for assessment and ongoing review of modi-
21 fied risk tobacco products. Such regulations or guid-
22 ance shall—

23 “(A) to the extent that adequate scientific
24 evidence exists, establish minimum standards
25 for scientific studies needed prior to issuing an

1 order under subsection (g) to show that a sub-
2 stantial reduction in morbidity or mortality
3 among individual tobacco users occurs for prod-
4 ucts described in subsection (g)(1) or is reason-
5 ably likely for products described in subsection
6 (g)(2);

7 “(B) include validated biomarkers, inter-
8 mediate clinical endpoints, and other feasible
9 outcome measures, as appropriate;

10 “(C) establish minimum standards for
11 postmarket studies, that shall include regular
12 and long-term assessments of health outcomes
13 and mortality, intermediate clinical endpoints,
14 consumer perception of harm reduction, and the
15 impact on quitting behavior and new use of to-
16 bacco products, as appropriate;

17 “(D) establish minimum standards for re-
18 quired postmarket surveillance, including ongo-
19 ing assessments of consumer perception;

20 “(E) require that data from the required
21 studies and surveillance be made available to
22 the Secretary prior to the decision on renewal
23 of a modified risk tobacco product; and

1 “(F) establish a reasonable timetable for
2 the Secretary to review an application under
3 this section.

4 “(2) CONSULTATION.—The regulations or guid-
5 ance issued under paragraph (1) shall be developed
6 in consultation with the Institute of Medicine, and
7 with the input of other appropriate scientific and
8 medical experts, on the design and conduct of such
9 studies and surveillance.

10 “(3) REVISION.—The regulations or guidance
11 under paragraph (1) shall be revised on a regular
12 basis as new scientific information becomes avail-
13 able.

14 “(4) NEW TOBACCO PRODUCTS.—Not later
15 than 2 years after the date of enactment of the
16 Family Smoking Prevention and Tobacco Control
17 Act, the Secretary shall issue a regulation or guid-
18 ance that permits the filing of a single application
19 for any tobacco product that is a new tobacco prod-
20 uct under section 910 and which the applicant seeks
21 to commercially market under this section.

22 “(m) DISTRIBUTORS.—Except as provided in this
23 section, no distributor may take any action, after the date
24 of enactment of the Family Smoking Prevention and To-
25 bacco Control Act, with respect to a tobacco product that

1 would reasonably be expected to result in consumers be-
2 lieving that the tobacco product or its smoke may present
3 a lower risk of disease or is less harmful than one or more
4 commercially marketed tobacco products, or presents a re-
5 duced exposure to, or does not contain or is free of, a sub-
6 stance or substances.

7 **“SEC. 912. JUDICIAL REVIEW.**

8 “(a) RIGHT TO REVIEW.—

9 “(1) IN GENERAL.—Not later than 30 days
10 after—

11 “(A) the promulgation of a regulation
12 under section 907 establishing, amending, or
13 revoking a tobacco product standard; or

14 “(B) a denial of an application under sec-
15 tion 910(c),

16 any person adversely affected by such regulation or
17 denial may file a petition for judicial review of such
18 regulation or denial with the United States Court of
19 Appeals for the District of Columbia or for the cir-
20 cuit in which such person resides or has their prin-
21 cipal place of business.

22 “(2) REQUIREMENTS.—

23 “(A) COPY OF PETITION.—A copy of the
24 petition filed under paragraph (1) shall be

1 transmitted by the clerk of the court involved to
2 the Secretary.

3 “(B) RECORD OF PROCEEDINGS.—On re-
4 ceipt of a petition under subparagraph (A), the
5 Secretary shall file in the court in which such
6 petition was filed—

7 “(i) the record of the proceedings on
8 which the regulation or order was based;
9 and

10 “(ii) a statement of the reasons for
11 the issuance of such a regulation or order.

12 “(C) DEFINITION OF RECORD.—In this
13 section, the term ‘record’ means—

14 “(i) all notices and other matter pub-
15 lished in the Federal Register with respect
16 to the regulation or order reviewed;

17 “(ii) all information submitted to the
18 Secretary with respect to such regulation
19 or order;

20 “(iii) proceedings of any panel or ad-
21 visory committee with respect to such reg-
22 ulation or order;

23 “(iv) any hearing held with respect to
24 such regulation or order; and

1 “(v) any other information identified
2 by the Secretary, in the administrative pro-
3 ceeding held with respect to such regula-
4 tion or order, as being relevant to such
5 regulation or order.

6 “(b) STANDARD OF REVIEW.—Upon the filing of the
7 petition under subsection (a) for judicial review of a regu-
8 lation or order, the court shall have jurisdiction to review
9 the regulation or order in accordance with chapter 7 of
10 title 5, United States Code, and to grant appropriate re-
11 lief, including interim relief, as provided for in such chap-
12 ter. A regulation or denial described in subsection (a) shall
13 be reviewed in accordance with section 706(2)(A) of title
14 5, United States Code.

15 “(c) FINALITY OF JUDGMENT.—The judgment of the
16 court affirming or setting aside, in whole or in part, any
17 regulation or order shall be final, subject to review by the
18 Supreme Court of the United States upon certiorari or
19 certification, as provided in section 1254 of title 28,
20 United States Code.

21 “(d) OTHER REMEDIES.—The remedies provided for
22 in this section shall be in addition to, and not in lieu of,
23 any other remedies provided by law.

24 “(e) REGULATIONS AND ORDERS MUST RECITE
25 BASIS IN RECORD.—To facilitate judicial review, a regula-

1 tion or order issued under section 906, 907, 908, 909,
2 910, or 916 shall contain a statement of the reasons for
3 the issuance of such regulation or order in the record of
4 the proceedings held in connection with its issuance.

5 **“SEC. 913. EQUAL TREATMENT OF RETAIL OUTLETS.**

6 “The Secretary shall issue regulations to require that
7 retail establishments for which the predominant business
8 is the sale of tobacco products comply with any advertising
9 restrictions applicable to retail establishments accessible
10 to individuals under the age of 18.

11 **“SEC. 914. JURISDICTION OF AND COORDINATION WITH**
12 **THE FEDERAL TRADE COMMISSION.**

13 “(a) JURISDICTION.—

14 “(1) IN GENERAL.—Except where expressly
15 provided in this chapter, nothing in this chapter
16 shall be construed as limiting or diminishing the au-
17 thority of the Federal Trade Commission to enforce
18 the laws under its jurisdiction with respect to the
19 advertising, sale, or distribution of tobacco products.

20 “(2) ENFORCEMENT.—Any advertising that vio-
21 lates this chapter or a provision of the regulations
22 referred to in section 102 of the Family Smoking
23 Prevention and Tobacco Control Act, is an unfair or
24 deceptive act or practice under section 5(a) of the
25 Federal Trade Commission Act and shall be consid-

1 ered a violation of a rule promulgated under section
2 18 of that Act.

3 “(b) COORDINATION.—With respect to the require-
4 ments of section 4 of the Federal Cigarette Labeling and
5 Advertising Act and section 3 of the Comprehensive
6 Smokeless Tobacco Health Education Act of 1986—

7 “(1) the Chairman of the Federal Trade Com-
8 mission shall coordinate with the Secretary con-
9 cerning the enforcement of such Act as such enforce-
10 ment relates to unfair or deceptive acts or practices
11 in the advertising of cigarettes or smokeless tobacco;
12 and

13 “(2) the Secretary shall consult with the Chair-
14 man of such Commission in revising the label state-
15 ments and requirements under such sections.

16 **“SEC. 915. REGULATION REQUIREMENT.**

17 “(a) TESTING, REPORTING, AND DISCLOSURE.—Not
18 later than 36 months after the date of enactment of the
19 Family Smoking Prevention and Tobacco Control Act, the
20 Secretary shall promulgate regulations under this Act that
21 meet the requirements of subsection (b).

22 “(b) CONTENTS OF RULES.—The regulations pro-
23 mulgated under subsection (a)—

24 “(1) shall require testing and reporting of to-
25 bacco product constituents, ingredients, and addi-

1 tives, including smoke constituents, by brand and
2 subbrand that the Secretary determines should be
3 tested to protect the public health, provided that, for
4 purposes of the testing requirements of this para-
5 graph, tobacco products manufactured and sold by a
6 single tobacco product manufacturer that are iden-
7 tical in all respects except the labels, packaging de-
8 sign, logo, trade dress, trademark, brand name, or
9 any combination thereof, shall be considered as a
10 single brand; and

11 “(2) may require that tobacco product manu-
12 facturers, packagers, or importers make disclosures
13 relating to the results of the testing of tar and nico-
14 tine through labels or advertising or other appro-
15 priate means, and make disclosures regarding the
16 results of the testing of other constituents, including
17 smoke constituents, ingredients, or additives, that
18 the Secretary determines should be disclosed to the
19 public to protect the public health and will not mis-
20 lead consumers about the risk of tobacco-related dis-
21 ease.

22 “(c) AUTHORITY.—The Secretary shall have the au-
23 thority under this chapter to conduct or to require the
24 testing, reporting, or disclosure of tobacco product con-
25 stituents, including smoke constituents.

1 “(d) SMALL TOBACCO PRODUCT MANUFACTUR-
2 ERS.—

3 “(1) FIRST COMPLIANCE DATE.—The initial
4 regulations promulgated under subsection (a) shall
5 not impose requirements on small tobacco product
6 manufacturers before the later of—

7 “(A) the end of the 2-year period following
8 the final promulgation of such regulations; and

9 “(B) the initial date set by the Secretary
10 for compliance with such regulations by manu-
11 facturers that are not small tobacco product
12 manufacturers.

13 “(2) TESTING AND REPORTING INITIAL COM-
14 PLIANCE PERIOD.—

15 “(A) 4-YEAR PERIOD.—The initial regula-
16 tions promulgated under subsection (a) shall
17 give each small tobacco product manufacturer a
18 4-year period over which to conduct testing and
19 reporting for all of its tobacco products. Subject
20 to paragraph (1), the end of the first year of
21 such 4-year period shall coincide with the initial
22 date of compliance under this section set by the
23 Secretary with respect to manufacturers that
24 are not small tobacco product manufacturers or
25 the end of the 2-year period following the final

1 promulgation of such regulations, as described
2 in paragraph (1)(A). A small tobacco product
3 manufacturer shall be required—

4 “(i) to conduct such testing and re-
5 porting for 25 percent of its tobacco prod-
6 ucts during each year of such 4-year pe-
7 riod; and

8 “(ii) to conduct such testing and re-
9 porting for its largest-selling tobacco prod-
10 ucts (as determined by the Secretary) be-
11 fore its other tobacco products, or in such
12 other order of priority as determined by
13 the Secretary.

14 “(B) CASE-BY-CASE DELAY.—Notwith-
15 standing subparagraph (A), the Secretary may,
16 on a case-by-case basis, delay the date by which
17 an individual small tobacco product manufac-
18 turer must conduct testing and reporting for its
19 tobacco products under this section based upon
20 a showing of undue hardship to such manufac-
21 turer. Notwithstanding the preceding sentence,
22 the Secretary shall not extend the deadline for
23 a small tobacco product manufacturer to con-
24 duct testing and reporting for all of its tobacco
25 products beyond a total of 5 years after the ini-

1 tial date of compliance under this section set by
2 the Secretary with respect to manufacturers
3 that are not small tobacco product manufactur-
4 ers.

5 “(3) SUBSEQUENT AND ADDITIONAL TESTING
6 AND REPORTING.—The regulations promulgated
7 under subsection (a) shall provide that, with respect
8 to any subsequent or additional testing and report-
9 ing of tobacco products required under this section,
10 such testing and reporting by a small tobacco prod-
11 uct manufacturer shall be conducted in accordance
12 with the timeframes described in paragraph (2)(A),
13 except that, in the case of a new product, or if there
14 has been a modification described in section
15 910(a)(1)(B) of any product of a small tobacco
16 product manufacturer since the last testing and re-
17 porting required under this section, the Secretary
18 shall require that any subsequent or additional test-
19 ing and reporting be conducted in accordance with
20 the same timeframe applicable to manufacturers
21 that are not small tobacco product manufacturers.

22 “(4) JOINT LABORATORY TESTING SERVICES.—
23 The Secretary shall allow any 2 or more small to-
24 bacco product manufacturers to join together to pur-
25 chase laboratory testing services required by this

1 section on a group basis in order to ensure that such
2 manufacturers receive access to, and fair pricing of,
3 such testing services.

4 “(e) EXTENSIONS FOR LIMITED LABORATORY CA-
5 PACITY.—

6 “(1) IN GENERAL.—The regulations promul-
7 gated under subsection (a) shall provide that a small
8 tobacco product manufacturer shall not be consid-
9 ered to be in violation of this section before the
10 deadline applicable under paragraphs (3) and (4),
11 if—

12 “(A) the tobacco products of such manu-
13 facturer are in compliance with all other re-
14 quirements of this chapter; and

15 “(B) the conditions described in paragraph
16 (2) are met.

17 “(2) CONDITIONS.—Notwithstanding the re-
18 quirements of this section, the Secretary may delay
19 the date by which a small tobacco product manufac-
20 turer must be in compliance with the testing and re-
21 porting required by this section until such time as
22 the testing is reported if, not later than 90 days be-
23 fore the deadline for reporting in accordance with
24 this section, a small tobacco product manufacturer

1 provides evidence to the Secretary demonstrating
2 that—

3 “(A) the manufacturer has submitted the
4 required products for testing to a laboratory
5 and has done so sufficiently in advance of the
6 deadline to create a reasonable expectation of
7 completion by the deadline;

8 “(B) the products currently are awaiting
9 testing by the laboratory; and

10 “(C) neither that laboratory nor any other
11 laboratory is able to complete testing by the
12 deadline at customary, nonexpedited testing
13 fees.

14 “(3) EXTENSION.—The Secretary, taking into
15 account the laboratory testing capacity that is avail-
16 able to tobacco product manufacturers, shall review
17 and verify the evidence submitted by a small tobacco
18 product manufacturer in accordance with paragraph
19 (2). If the Secretary finds that the conditions de-
20 scribed in such paragraph are met, the Secretary
21 shall notify the small tobacco product manufacturer
22 that the manufacturer shall not be considered to be
23 in violation of the testing and reporting require-
24 ments of this section until the testing is reported or
25 until 1 year after the reporting deadline has passed,

1 whichever occurs sooner. If, however, the Secretary
2 has not made a finding before the reporting dead-
3 line, the manufacturer shall not be considered to be
4 in violation of such requirements until the Secretary
5 finds that the conditions described in paragraph (2)
6 have not been met, or until 1 year after the report-
7 ing deadline, whichever occurs sooner.

8 “(4) ADDITIONAL EXTENSION.—In addition to
9 the time that may be provided under paragraph (3),
10 the Secretary may provide further extensions of
11 time, in increments of no more than 1 year, for re-
12 quired testing and reporting to occur if the Sec-
13 retary determines, based on evidence properly and
14 timely submitted by a small tobacco product manu-
15 facturer in accordance with paragraph (2), that a
16 lack of available laboratory capacity prevents the
17 manufacturer from completing the required testing
18 during the period described in paragraph (3).

19 “(f) RULE OF CONSTRUCTION.—Nothing in sub-
20 section (d) or (e) shall be construed to authorize the exten-
21 sion of any deadline, or to otherwise affect any timeframe,
22 under any provision of this Act or the Family Smoking
23 Prevention and Tobacco Control Act other than this sec-
24 tion.

1 **“SEC. 916. PRESERVATION OF STATE AND LOCAL AUTHOR-**
2 **ITY.**

3 “(a) IN GENERAL.—

4 “(1) PRESERVATION.—Except as provided in
5 paragraph (2)(A), nothing in this chapter, or rules
6 promulgated under this chapter, shall be construed
7 to limit the authority of a Federal agency (including
8 the Armed Forces), a State or political subdivision
9 of a State, or the government of an Indian tribe to
10 enact, adopt, promulgate, and enforce any law, rule,
11 regulation, or other measure with respect to tobacco
12 products that is in addition to, or more stringent
13 than, requirements established under this chapter,
14 including a law, rule, regulation, or other measure
15 relating to or prohibiting the sale, distribution, pos-
16 session, exposure to, access to, advertising and pro-
17 motion of, or use of tobacco products by individuals
18 of any age, information reporting to the State, or
19 measures relating to fire safety standards for to-
20 bacco products. No provision of this chapter shall
21 limit or otherwise affect any State, Tribal, or local
22 taxation of tobacco products.

23 “(2) PREEMPTION OF CERTAIN STATE AND
24 LOCAL REQUIREMENTS.—

25 “(A) IN GENERAL.—No State or political
26 subdivision of a State may establish or continue

1 in effect with respect to a tobacco product any
2 requirement which is different from, or in addi-
3 tion to, any requirement under the provisions of
4 this chapter relating to tobacco product stand-
5 ards, premarket review, adulteration, mis-
6 branding, labeling, registration, good manufac-
7 turing standards, or modified risk tobacco prod-
8 ucts.

9 “(B) EXCEPTION.—Subparagraph (A)
10 does not apply to requirements relating to the
11 sale, distribution, possession, information re-
12 porting to the State, exposure to, access to, the
13 advertising and promotion of, or use of, tobacco
14 products by individuals of any age, or relating
15 to fire safety standards for tobacco products.
16 Information disclosed to a State under subpara-
17 graph (A) that is exempt from disclosure under
18 section 552(b)(4) of title 5, United States Code,
19 shall be treated as a trade secret and confiden-
20 tial information by the State.

21 “(b) RULE OF CONSTRUCTION REGARDING PRODUCT
22 LIABILITY.—No provision of this chapter relating to a to-
23 bacco product shall be construed to modify or otherwise
24 affect any action or the liability of any person under the
25 product liability law of any State.

1 **“SEC. 917. TOBACCO PRODUCTS SCIENTIFIC ADVISORY**
2 **COMMITTEE.**

3 “(a) ESTABLISHMENT.—Not later than 6 months
4 after the date of enactment of the Family Smoking Pre-
5 vention and Tobacco Control Act, the Secretary shall es-
6 tablish a 12-member advisory committee, to be known as
7 the Tobacco Products Scientific Advisory Committee (in
8 this section referred to as the ‘Advisory Committee’).

9 “(b) MEMBERSHIP.—

10 “(1) IN GENERAL.—

11 “(A) MEMBERS.—The Secretary shall ap-
12 point as members of the Tobacco Products Sci-
13 entific Advisory Committee individuals who are
14 technically qualified by training and experience
15 in medicine, medical ethics, science, or tech-
16 nology involving the manufacture, evaluation, or
17 use of tobacco products, who are of appro-
18 priately diversified professional backgrounds.
19 The committee shall be composed of—

20 “(i) 7 individuals who are physicians,
21 dentists, scientists, or health care profes-
22 sionals practicing in the area of oncology,
23 pulmonology, cardiology, toxicology, phar-
24 macology, addiction, or any other relevant
25 specialty;

1 “(ii) 1 individual who is an officer or
2 employee of a State or local government or
3 of the Federal Government;

4 “(iii) 1 individual as a representative
5 of the general public;

6 “(iv) 1 individual as a representative
7 of the interests of the tobacco manufac-
8 turing industry;

9 “(v) 1 individual as a representative
10 of the interests of the small business to-
11 bacco manufacturing industry, which posi-
12 tion may be filled on a rotating, sequential
13 basis by representatives of different small
14 business tobacco manufacturers based on
15 areas of expertise relevant to the topics
16 being considered by the Advisory Com-
17 mittee; and

18 “(vi) 1 individual as a representative
19 of the interests of the tobacco growers.

20 “(B) NONVOTING MEMBERS.—The mem-
21 bers of the committee appointed under clauses
22 (iv), (v), and (vi) of subparagraph (A) shall
23 serve as consultants to those described in
24 clauses (i) through (iii) of subparagraph (A)
25 and shall be nonvoting representatives.

1 “(C) CONFLICTS OF INTEREST.—No mem-
2 bers of the committee, other than members ap-
3 pointed pursuant to clauses (iv), (v), and (vi) of
4 subparagraph (A) shall, during the member’s
5 tenure on the committee or for the 18-month
6 period prior to becoming such a member, re-
7 ceive any salary, grants, or other payments or
8 support from any business that manufactures,
9 distributes, markets, or sells cigarettes or other
10 tobacco products.

11 “(2) LIMITATION.—The Secretary may not ap-
12 point to the Advisory Committee any individual who
13 is in the regular full-time employ of the Food and
14 Drug Administration or any agency responsible for
15 the enforcement of this Act. The Secretary may ap-
16 point Federal officials as ex officio members.

17 “(3) CHAIRPERSON.—The Secretary shall des-
18 ignate 1 of the members appointed under clauses (i),
19 (ii), and (iii) of paragraph (1)(A) to serve as chair-
20 person.

21 “(c) DUTIES.—The Tobacco Products Scientific Ad-
22 visory Committee shall provide advice, information, and
23 recommendations to the Secretary—

24 “(1) as provided in this chapter;

1 “(2) on the effects of the alteration of the nico-
2 tine yields from tobacco products;

3 “(3) on whether there is a threshold level below
4 which nicotine yields do not produce dependence on
5 the tobacco product involved; and

6 “(4) on its review of other safety, dependence,
7 or health issues relating to tobacco products as re-
8 quested by the Secretary.

9 “(d) COMPENSATION; SUPPORT; FACA.—

10 “(1) COMPENSATION AND TRAVEL.—Members
11 of the Advisory Committee who are not officers or
12 employees of the United States, while attending con-
13 ferences or meetings of the committee or otherwise
14 engaged in its business, shall be entitled to receive
15 compensation at rates to be fixed by the Secretary,
16 which may not exceed the daily equivalent of the
17 rate in effect under the Senior Executive Schedule
18 under section 5382 of title 5, United States Code,
19 for each day (including travel time) they are so en-
20 gaged; and while so serving away from their homes
21 or regular places of business each member may be
22 allowed travel expenses, including per diem in lieu of
23 subsistence, as authorized by section 5703 of title 5,
24 United States Code, for persons in the Government
25 service employed intermittently.

1 “(2) ADMINISTRATIVE SUPPORT.—The Sec-
2 retary shall furnish the Advisory Committee clerical
3 and other assistance.

4 “(3) NONAPPLICATION OF FACa.—Section 14 of
5 the Federal Advisory Committee Act does not apply
6 to the Advisory Committee.

7 “(e) PROCEEDINGS OF ADVISORY PANELS AND COM-
8 MITTEES.—The Advisory Committee shall make and
9 maintain a transcript of any proceeding of the panel or
10 committee. Each such panel and committee shall delete
11 from any transcript made under this subsection informa-
12 tion which is exempt from disclosure under section 552(b)
13 of title 5, United States Code.

14 **“SEC. 918. DRUG PRODUCTS USED TO TREAT TOBACCO DE-**
15 **PENDENCE.**

16 “(a) IN GENERAL.—The Secretary shall—

17 “(1) at the request of the applicant, consider
18 designating products for smoking cessation, includ-
19 ing nicotine replacement products as fast track re-
20 search and approval products within the meaning of
21 section 506;

22 “(2) consider approving the extended use of nic-
23 otine replacement products (such as nicotine patch-
24 es, nicotine gum, and nicotine lozenges) for the
25 treatment of tobacco dependence; and

1 “(3) review and consider the evidence for addi-
2 tional indications for nicotine replacement products,
3 such as for craving relief or relapse prevention.

4 “(b) REPORT ON INNOVATIVE PRODUCTS.—

5 “(1) IN GENERAL.—Not later than 3 years
6 after the date of enactment of the Family Smoking
7 Prevention and Tobacco Control Act, the Secretary,
8 after consultation with recognized scientific, medical,
9 and public health experts (including both Federal
10 agencies and nongovernmental entities, the Institute
11 of Medicine of the National Academy of Sciences,
12 and the Society for Research on Nicotine and To-
13 bacco), shall submit to the Congress a report that
14 examines how best to regulate, promote, and encour-
15 age the development of innovative products and
16 treatments (including nicotine-based and non-nico-
17 tine-based products and treatments) to better
18 achieve, in a manner that best protects and pro-
19 motes the public health—

20 “(A) total abstinence from tobacco use;

21 “(B) reductions in consumption of tobacco;

22 and

23 “(C) reductions in the harm associated
24 with continued tobacco use.

1 “(2) RECOMMENDATIONS.—The report under
2 paragraph (1) shall include the recommendations of
3 the Secretary on how the Food and Drug Adminis-
4 tration should coordinate and facilitate the exchange
5 of information on such innovative products and
6 treatments among relevant offices and centers within
7 the Administration and within the National Insti-
8 tutes of Health, the Centers for Disease Control and
9 Prevention, and other relevant agencies.

10 **“SEC. 919. USER FEES.**

11 “(a) ESTABLISHMENT OF QUARTERLY FEE.—Begin-
12 ning on the date of enactment of the Family Smoking Pre-
13 vention and Tobacco Control Act, the Secretary shall in
14 accordance with this section assess user fees on, and col-
15 lect such fees from, each manufacturer and importer of
16 tobacco products subject to this chapter. The fees shall
17 be assessed and collected with respect to each quarter of
18 each fiscal year, and the total amount assessed and col-
19 lected for a fiscal year shall be the amount specified in
20 subsection (b)(1) for such year, subject to subsection (c).

21 “(b) ASSESSMENT OF USER FEE.—

22 “(1) AMOUNT OF ASSESSMENT.—The total
23 amount of user fees authorized to be assessed and
24 collected under subsection (a) for a fiscal year is the
25 following, as applicable to the fiscal year involved:

1 “(A) For fiscal year 2009, \$85,000,000
2 (subject to subsection (e)).

3 “(B) For fiscal year 2010, \$235,000,000.

4 “(C) For fiscal year 2011, \$450,000,000.

5 “(D) For fiscal year 2012, \$477,000,000.

6 “(E) For fiscal year 2013, \$505,000,000.

7 “(F) For fiscal year 2014, \$534,000,000.

8 “(G) For fiscal year 2015, \$566,000,000.

9 “(H) For fiscal year 2016, \$599,000,000.

10 “(I) For fiscal year 2017, \$635,000,000.

11 “(J) For fiscal year 2018, \$672,000,000.

12 “(K) For fiscal year 2019 and each subse-
13 quent fiscal year, \$712,000,000.

14 “(2) ALLOCATIONS OF ASSESSMENT BY CLASS
15 OF TOBACCO PRODUCTS.—

16 “(A) IN GENERAL.—The total user fees as-
17 sessed and collected under subsection (a) each
18 fiscal year with respect to each class of tobacco
19 products shall be an amount that is equal to
20 the applicable percentage of each class for the
21 fiscal year multiplied by the amount specified in
22 paragraph (1) for the fiscal year.

23 “(B) APPLICABLE PERCENTAGE.—

24 “(i) IN GENERAL.—For purposes of
25 subparagraph (A), the applicable percent-

1 age for a fiscal year for each of the fol-
2 lowing classes of tobacco products shall be
3 determined in accordance with clause (ii):

4 “(I) Cigarettes.

5 “(II) Cigars, including small ci-
6 gars and cigars other than small ci-
7 gars.

8 “(III) Snuff.

9 “(IV) Chewing tobacco.

10 “(V) Pipe tobacco.

11 “(VI) Roll-your-own tobacco.

12 “(ii) ALLOCATIONS.—The applicable
13 percentage of each class of tobacco product
14 described in clause (i) for a fiscal year
15 shall be the percentage determined under
16 section 625(c) of Public Law 108–357 for
17 each such class of product for such fiscal
18 year.

19 “(iii) REQUIREMENT OF REGULA-
20 TIONS.—Notwithstanding clause (ii), no
21 user fees shall be assessed on a class of to-
22 bacco products unless such class of tobacco
23 products is listed in section 901(b) or is
24 deemed by the Secretary in a regulation

1 under section 901(b) to be subject to this
2 chapter.

3 “(iv) REALLOCATIONS.—In the case
4 of a class of tobacco products that is not
5 listed in section 901(b) or deemed by the
6 Secretary in a regulation under section
7 901(b) to be subject to this chapter, the
8 amount of user fees that would otherwise
9 be assessed to such class of tobacco prod-
10 ucts shall be reallocated to the classes of
11 tobacco products that are subject to this
12 chapter in the same manner and based on
13 the same relative percentages otherwise de-
14 termined under clause (ii).

15 “(3) DETERMINATION OF USER FEE BY COM-
16 PANY.—

17 “(A) IN GENERAL.—The total user fee to
18 be paid by each manufacturer or importer of a
19 particular class of tobacco products shall be de-
20 termined for each quarter by multiplying—

21 “(i) such manufacturer’s or importer’s
22 percentage share as determined under
23 paragraph (4); by

24 “(ii) the portion of the user fee
25 amount for the current quarter to be as-

1 sessed on all manufacturers and importers
2 of such class of tobacco products as deter-
3 mined under paragraph (2).

4 “(B) NO FEE IN EXCESS OF PERCENTAGE
5 SHARE.—No manufacturer or importer of to-
6 bacco products shall be required to pay a user
7 fee in excess of the percentage share of such
8 manufacturer or importer.

9 “(4) ALLOCATION OF ASSESSMENT WITHIN
10 EACH CLASS OF TOBACCO PRODUCT.—The percent-
11 age share of each manufacturer or importer of a
12 particular class of tobacco products of the total user
13 fee to be paid by all manufacturers or importers of
14 that class of tobacco products shall be the percent-
15 age determined for purposes of allocations under
16 subsections (e) through (h) of section 625 of Public
17 Law 108–357.

18 “(5) ALLOCATION FOR CIGARS.—Notwith-
19 standing paragraph (4), if a user fee assessment is
20 imposed on cigars, the percentage share of each
21 manufacturer or importer of cigars shall be based on
22 the excise taxes paid by such manufacturer or im-
23 porter during the prior fiscal year.

24 “(6) TIMING OF ASSESSMENT.—The Secretary
25 shall notify each manufacturer and importer of to-

1 bacco products subject to this section of the amount
2 of the quarterly assessment imposed on such manu-
3 facturer or importer under this subsection for each
4 quarter of each fiscal year. Such notifications shall
5 occur not later than 30 days prior to the end of the
6 quarter for which such assessment is made, and pay-
7 ments of all assessments shall be made by the last
8 day of the quarter involved.

9 “(7) MEMORANDUM OF UNDERSTANDING.—

10 “(A) IN GENERAL.—The Secretary shall
11 request the appropriate Federal agency to enter
12 into a memorandum of understanding that pro-
13 vides for the regular and timely transfer from
14 the head of such agency to the Secretary of the
15 information described in paragraphs (2)(B)(ii)
16 and (4) and all necessary information regarding
17 all tobacco product manufacturers and import-
18 ers required to pay user fees. The Secretary
19 shall maintain all disclosure restrictions estab-
20 lished by the head of such agency regarding the
21 information provided under the memorandum of
22 understanding.

23 “(B) ASSURANCES.—Beginning not later
24 than fiscal year 2015, and for each subsequent
25 fiscal year, the Secretary shall ensure that the

1 Food and Drug Administration is able to deter-
2 mine the applicable percentages described in
3 paragraph (2) and the percentage shares de-
4 scribed in paragraph (4). The Secretary may
5 carry out this subparagraph by entering into a
6 contract with the head of the Federal agency
7 referred to in subparagraph (A) to continue to
8 provide the necessary information.

9 “(c) CREDITING AND AVAILABILITY OF FEES.—

10 “(1) IN GENERAL.—Fees authorized under sub-
11 section (a) shall be collected and available for obliga-
12 tion only to the extent and in the amount provided
13 in advance in appropriations Acts. Such fees are au-
14 thorized to remain available until expended. Such
15 sums as may be necessary may be transferred from
16 the Food and Drug Administration salaries and ex-
17 penses appropriation account without fiscal year lim-
18 itation to such appropriation account for salaries
19 and expenses with such fiscal year limitation.

20 “(2) AVAILABILITY.—

21 “(A) IN GENERAL.—Fees appropriated
22 under paragraph (3) are available only for the
23 purpose of paying the costs of the activities of
24 the Food and Drug Administration related to
25 the regulation of tobacco products under this

1 chapter and the Family Smoking Prevention
2 and Tobacco Control Act. No fees collected
3 under subsection (a) may be used for any other
4 costs.

5 “(B) PROHIBITION AGAINST USE OF
6 OTHER FUNDS.—

7 “(i) IN GENERAL.—Except as pro-
8 vided in clause (ii), fees collected under
9 subsection (a) are the only funds author-
10 ized to be made available for the purpose
11 described in subparagraph (A).

12 “(ii) STARTUP COSTS.—Clause (i)
13 does not apply until the date on which the
14 Secretary has collected fees under sub-
15 section (a) for 2 fiscal year quarters. Until
16 such date, other amounts available to the
17 Food and Drug Administration (excluding
18 fees collected under subsection (a)) are au-
19 thorized to be made available to pay the
20 costs described in subparagraph (A), pro-
21 vided that such amounts are reimbursed
22 through fees collected under subsection (a).

23 “(3) AUTHORIZATION OF APPROPRIATIONS.—
24 For fiscal year 2009 and each subsequent fiscal
25 year, there is authorized to be appropriated for fees

1 under this section an amount equal to the amount
2 specified in subsection (b)(1) for the fiscal year.

3 “(d) COLLECTION OF UNPAID FEES.—In any case
4 where the Secretary does not receive payment of a fee as-
5 sessed under subsection (a) within 30 days after it is due,
6 such fee shall be treated as a claim of the United States
7 Government subject to subchapter II of chapter 37 of title
8 31, United States Code.

9 “(e) APPLICABILITY TO FISCAL YEAR 2009.—If the
10 date of enactment of the Family Smoking Prevention and
11 Tobacco Control Act occurs during fiscal year 2009, the
12 following applies, subject to subsection (c):

13 “(1) The Secretary shall determine the fees
14 that would apply for a single quarter of such fiscal
15 year according to the application of subsection (b) to
16 the amount specified in paragraph (1)(A) of such
17 subsection (referred to in this subsection as the
18 ‘quarterly fee amounts’).

19 “(2) For the quarter in which such date of en-
20 actment occurs, the amount of fees assessed shall be
21 a pro rata amount, determined according to the
22 number of days remaining in the quarter (including
23 such date of enactment) and according to the daily
24 equivalent of the quarterly fee amounts. Fees as-

1 sessed under the preceding sentence shall not be col-
2 lected until the next quarter.

3 “(3) For the quarter following the quarter to
4 which paragraph (2) applies, the full quarterly fee
5 amounts shall be assessed and collected, in addition
6 to collection of the pro rata fees assessed under
7 paragraph (2).”.

8 **SEC. 102. FINAL RULE.**

9 (a) CIGARETTES AND SMOKELESS TOBACCO.—

10 (1) IN GENERAL.—On the first day of publica-
11 tion of the Federal Register that is 180 days or
12 more after the date of enactment of this Act, the
13 Secretary of Health and Human Services shall pub-
14 lish in the Federal Register a final rule regarding
15 cigarettes and smokeless tobacco, which—

16 (A) is deemed to be issued under chapter
17 9 of the Federal Food, Drug, and Cosmetic
18 Act, as added by section 101 of this Act; and

19 (B) shall be deemed to be in compliance
20 with all applicable provisions of chapter 5 of
21 title 5, United States Code, and all other provi-
22 sions of law relating to rulemaking procedures.

23 (2) CONTENTS OF RULE.—Except as provided
24 in this subsection, the final rule published under
25 paragraph (1), shall be identical in its provisions to

1 part 897 of the regulations promulgated by the Sec-
2 retary of Health and Human Services in the August
3 28, 1996, issue of the Federal Register (61 Fed.
4 Reg., 44615–44618). Such rule shall—

5 (A) provide for the designation of jurisdic-
6 tional authority that is in accordance with this
7 subsection in accordance with this Act and the
8 amendments made by this Act;

9 (B) strike Subpart C—Labels and section
10 897.32(c);

11 (C) strike paragraphs (a), (b), and (i) of
12 section 897.3 and insert definitions of the terms
13 “cigarette”, “cigarette tobacco,” and “smoke-
14 less tobacco” as defined in section 900 of the
15 Federal Food, Drug, and Cosmetic Act;

16 (D) insert “or roll-your-own paper” in sec-
17 tion 897.34(a) after “other than cigarettes or
18 smokeless tobacco”;

19 (E) become effective on the date that is 1
20 year after the date of enactment of this Act;
21 and

22 (F) amend paragraph (d) of section 897.16
23 to read as follows:

24 “(d)(1) Except as provided in subparagraph (2), no
25 manufacturer, distributor, or retailer may distribute or

1 cause to be distributed any free samples of cigarettes,
2 smokeless tobacco, or other tobacco products (as such
3 term is defined in section 201 of the Federal Food, Drug,
4 and Cosmetic Act).

5 “(2)(A) Subparagraph (1) does not prohibit a manu-
6 facturer, distributor, or retailer from distributing or caus-
7 ing to be distributed free samples of smokeless tobacco
8 in a qualified adult-only facility.

9 “(B) This subparagraph does not affect the authority
10 of a State or local government to prohibit or otherwise
11 restrict the distribution of free samples of smokeless to-
12 bacco.

13 “(C) For purposes of this paragraph, the term ‘quali-
14 fied adult-only facility’ means a facility or restricted area
15 that—

16 “(i) requires each person present to provide to
17 a law enforcement officer (whether on or off duty)
18 or to a security guard licensed by a governmental
19 entity government-issued identification showing a
20 photograph and at least the minimum age estab-
21 lished by applicable law for the purchase of smoke-
22 less tobacco;

23 “(ii) does not sell, serve, or distribute alcohol;

24 “(iii) is not located adjacent to or immediately
25 across from (in any direction) a space that is used

1 primarily for youth-oriented marketing, promotional,
2 or other activities;

3 “(iv) is a temporary structure constructed, des-
4 igned, and operated as a distinct enclosed area for
5 the purpose of distributing free samples of smokeless
6 tobacco in accordance with this subparagraph; and

7 “(v) is enclosed by a barrier that—

8 “(I) is constructed of, or covered with, an
9 opaque material (except for entrances and
10 exits);

11 “(II) extends from no more than 12 inches
12 above the ground or floor (which area at the
13 bottom of the barrier must be covered with ma-
14 terial that restricts visibility but may allow air-
15 flow) to at least 8 feet above the ground or
16 floor (or to the ceiling); and

17 “(III) prevents persons outside the quali-
18 fied adult-only facility from seeing into the
19 qualified adult-only facility, unless they make
20 unreasonable efforts to do so; and

21 “(vi) does not display on its exterior—

22 “(I) any tobacco product advertising;

23 “(II) a brand name other than in conjunc-
24 tion with words for an area or enclosure to
25 identify an adult-only facility; or

1 “(III) any combination of words that
2 would imply to a reasonable observer that the
3 manufacturer, distributor, or retailer has a
4 sponsorship that would violate section
5 897.34(c).

6 “(D) Distribution of samples of smokeless tobacco
7 under this subparagraph permitted to be taken out of the
8 qualified adult-only facility shall be limited to 1 package
9 per adult consumer containing no more than 0.53 ounces
10 (15 grams) of smokeless tobacco. If such package of
11 smokeless tobacco contains individual portions of smoke-
12 less tobacco, the individual portions of smokeless tobacco
13 shall not exceed 8 individual portions and the collective
14 weight of such individual portions shall not exceed 0.53
15 ounces (15 grams). Any manufacturer, distributor, or re-
16 tailer who distributes or causes to be distributed free sam-
17 ples also shall take reasonable steps to ensure that the
18 above amounts are limited to one such package per adult
19 consumer per day.

20 “(3) Notwithstanding subparagraph (2), no manufac-
21 turer, distributor, or retailer may distribute or cause to
22 be distributed any free samples of smokeless tobacco—

23 “(A) to a sports team or entertainment group;
24 or

1 “(B) at any football, basketball, baseball, soc-
2 cer, or hockey event or any other sporting or enter-
3 tainment event determined by the Secretary to be
4 covered by this subparagraph.

5 “(4) The Secretary shall implement a program to en-
6 sure compliance with this paragraph and submit a report
7 to the Congress on such compliance not later than 18
8 months after the date of enactment of the Family Smok-
9 ing Prevention and Tobacco Control Act.

10 “(5) Nothing in this paragraph shall be construed to
11 authorize any person to distribute or cause to be distrib-
12 uted any sample of a tobacco product to any individual
13 who has not attained the minimum age established by ap-
14 plicable law for the purchase of such product.”.

15 (3) AMENDMENTS TO RULE.—Prior to making
16 amendments to the rule published under paragraph
17 (1), the Secretary shall promulgate a proposed rule
18 in accordance with chapter 5 of title 5, United
19 States Code.

20 (4) RULE OF CONSTRUCTION.—Except as pro-
21 vided in paragraph (3), nothing in this section shall
22 be construed to limit the authority of the Secretary
23 to amend, in accordance with chapter 5 of title 5,
24 United States Code, the regulation promulgated pur-
25 suant to this section, including the provisions of

1 such regulation relating to distribution of free sam-
2 ples.

3 (5) ENFORCEMENT OF RETAIL SALE PROVI-
4 SIONS.—The Secretary of Health and Human Serv-
5 ices shall ensure that the provisions of this Act, the
6 amendments made by this Act, and the imple-
7 menting regulations (including such provisions,
8 amendments, and regulations relating to the retail
9 sale of tobacco products) are enforced with respect
10 to the United States and Indian tribes.

11 (6) QUALIFIED ADULT-ONLY FACILITY.—A
12 qualified adult-only facility (as such term is defined
13 in section 897.16(d) of the final rule published
14 under paragraph (1)) that is also a retailer and that
15 commits a violation as a retailer shall not be subject
16 to the limitations in section 103(q) and shall be sub-
17 ject to penalties applicable to a qualified adult-only
18 facility.

19 (7) CONGRESSIONAL REVIEW PROVISIONS.—
20 Section 801 of title 5, United States Code, shall not
21 apply to the final rule published under paragraph
22 (1).

23 (b) LIMITATION ON ADVISORY OPINIONS.—As of the
24 date of enactment of this Act, the following documents
25 issued by the Food and Drug Administration shall not

1 constitute advisory opinions under section 10.85(d)(1) of
2 title 21, Code of Federal Regulations, except as they apply
3 to tobacco products, and shall not be cited by the Sec-
4 retary of Health and Human Services or the Food and
5 Drug Administration as binding precedent:

6 (1) The preamble to the proposed rule in the
7 document titled “Regulations Restricting the Sale
8 and Distribution of Cigarettes and Smokeless To-
9 bacco Products to Protect Children and Adoles-
10 cents” (60 Fed. Reg. 41314–41372 (August 11,
11 1995)).

12 (2) The document titled “Nicotine in Cigarettes
13 and Smokeless Tobacco Products is a Drug and
14 These Products Are Nicotine Delivery Devices
15 Under the Federal Food, Drug, and Cosmetic Act”
16 (60 Fed. Reg. 41453–41787 (August 11, 1995)).

17 (3) The preamble to the final rule in the docu-
18 ment titled “Regulations Restricting the Sale and
19 Distribution of Cigarettes and Smokeless Tobacco to
20 Protect Children and Adolescents” (61 Fed. Reg.
21 44396–44615 (August 28, 1996)).

22 (4) The document titled “Nicotine in Cigarettes
23 and Smokeless Tobacco is a Drug and These Prod-
24 ucts are Nicotine Delivery Devices Under the Fed-
25 eral Food, Drug, and Cosmetic Act; Jurisdictional

1 Determination” (61 Fed. Reg. 44619–45318 (Au-
2 gust 28, 1996)).

3 **SEC. 103. CONFORMING AND OTHER AMENDMENTS TO GEN-**
4 **ERAL PROVISIONS.**

5 (a) AMENDMENT OF FEDERAL FOOD, DRUG, AND
6 COSMETIC ACT.—Except as otherwise expressly provided,
7 whenever in this section an amendment is expressed in
8 terms of an amendment to, or repeal of, a section or other
9 provision, the reference is to a section or other provision
10 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
11 301 et seq.).

12 (b) SECTION 301.—Section 301 (21 U.S.C. 331) is
13 amended—

14 (1) in subsection (a), by inserting “tobacco
15 product,” after “device,”;

16 (2) in subsection (b), by inserting “tobacco
17 product,” after “device,”;

18 (3) in subsection (c), by inserting “tobacco
19 product,” after “device,”;

20 (4) in subsection (e)—

21 (A) by striking the period after “572(i)”;

22 and

23 (B) by striking “or 761 or the refusal to
24 permit access to” and inserting “761, 909, or
25 920 or the refusal to permit access to”;

1 (5) in subsection (g), by inserting “tobacco
2 product,” after “device,”;

3 (6) in subsection (h), by inserting “tobacco
4 product,” after “device,”;

5 (7) in subsection (j)—

6 (A) by striking the period after “573”; and

7 (B) by striking “708, or 721” and insert-
8 ing “708, 721, 904, 905, 906, 907, 908, 909,
9 or 920(b)”;

10 (8) in subsection (k), by inserting “tobacco
11 product,” after “device,”;

12 (9) by striking subsection (p) and inserting the
13 following:

14 “(p) The failure to register in accordance with section
15 510 or 905, the failure to provide any information re-
16 quired by section 510(j), 510(k), 905(i), or 905(j), or the
17 failure to provide a notice required by section 510(j)(2)
18 or 905(i)(3).”;

19 (10) by striking subsection (q)(1) and inserting
20 the following:

21 “(q)(1) The failure or refusal—

22 “(A) to comply with any requirement prescribed
23 under section 518, 520(g), 903(b), 907, 908, or 916;

1 “(B) to furnish any notification or other mate-
2 rial or information required by or under section 519,
3 520(g), 904, 909, or 920; or

4 “(C) to comply with a requirement under sec-
5 tion 522 or 913.”;

6 (11) in subsection (q)(2), by striking “device,”
7 and inserting “device or tobacco product,”;

8 (12) in subsection (r), by inserting “or tobacco
9 product” after the term “device” each time that
10 such term appears; and

11 (13) by adding at the end the following:

12 “(oo) The sale of tobacco products in violation of a
13 no-tobacco-sale order issued under section 303(f).

14 “(pp) The introduction or delivery for introduction
15 into interstate commerce of a tobacco product in violation
16 of section 911.

17 “(qq)(1) Forging, counterfeiting, simulating, or false-
18 ly representing, or without proper authority using any
19 mark, stamp (including tax stamp), tag, label, or other
20 identification device upon any tobacco product or con-
21 tainer or labeling thereof so as to render such tobacco
22 product a counterfeit tobacco product.

23 “(2) Making, selling, disposing of, or keeping in pos-
24 session, control, or custody, or concealing any punch, die,
25 plate, stone, or other item that is designed to print, im-

1 print, or reproduce the trademark, trade name, or other
2 identifying mark, imprint, or device of another or any like-
3 ness of any of the foregoing upon any tobacco product or
4 container or labeling thereof so as to render such tobacco
5 product a counterfeit tobacco product.

6 “(3) The doing of any act that causes a tobacco prod-
7 uct to be a counterfeit tobacco product, or the sale or dis-
8 pensing, or the holding for sale or dispensing, of a coun-
9 terfeit tobacco product.

10 “(rr) The charitable distribution of tobacco products.

11 “(ss) The failure of a manufacturer or distributor to
12 notify the Attorney General and the Secretary of the
13 Treasury of their knowledge of tobacco products used in
14 illicit trade.

15 “(tt) With respect to a tobacco product, any state-
16 ment directed to consumers through the media or through
17 the label, labeling, or advertising that would reasonably
18 be expected to result in consumers believing that the prod-
19 uct is regulated, inspected or approved by the Food and
20 Drug Administration, or that the product complies with
21 the requirements of the Food and Drug Administration,
22 including a statement or implication in the label, labeling,
23 or advertising of such product, and that could result in
24 consumers believing that the product is endorsed for use
25 by the Food and Drug Administration or in consumers

1 being misled about the harmfulness of the product because
2 of such regulation, inspection, or compliance.”.

3 (c) SECTION 303.—Section 303(f) (21 U.S.C. 333(f))
4 is amended—

5 (1) in paragraph (1)(A), by inserting “or to-
6 bacco products” after the term “devices” each place
7 such term appears;

8 (2) in paragraph (5)—

9 (A) in subparagraph (A)—

10 (i) by striking “assessed” the first
11 time it appears and inserting “assessed, or
12 a no-tobacco-sale order may be imposed,”;
13 and

14 (ii) by striking “penalty” the second
15 time it appears and inserting “penalty, or
16 upon whom a no-tobacco-sale order is to be
17 imposed,”;

18 (B) in subparagraph (B)—

19 (i) by inserting after “penalty,” the
20 following: “or the period to be covered by
21 a no-tobacco-sale order,”; and

22 (ii) by adding at the end the fol-
23 lowing: “A no-tobacco-sale order perma-
24 nently prohibiting an individual retail out-
25 let from selling tobacco products shall in-

1 clude provisions that allow the outlet, after
2 a specified period of time, to request that
3 the Secretary compromise, modify, or ter-
4 minate the order.”; and

5 (C) by adding at the end the following:

6 “(D) The Secretary may compromise, modify, or ter-
7 minate, with or without conditions, any no-tobacco-sale
8 order.”;

9 (3) in paragraph (6)—

10 (A) by inserting “or the imposition of a
11 no-tobacco-sale order” after the term “penalty”
12 each place such term appears; and

13 (B) by striking “issued.” and inserting
14 “issued, or on which the no-tobacco-sale order
15 was imposed, as the case may be.”; and

16 (4) by adding at the end the following:

17 “(8) If the Secretary finds that a person has
18 committed repeated violations of restrictions promul-
19 gated under section 906(d) at a particular retail out-
20 let then the Secretary may impose a no-tobacco-sale
21 order on that person prohibiting the sale of tobacco
22 products in that outlet. A no-tobacco-sale order may
23 be imposed with a civil penalty under paragraph (1).
24 Prior to the entry of a no-sale order under this para-
25 graph, a person shall be entitled to a hearing pursu-

1 ant to the procedures established through regula-
2 tions of the Food and Drug Administration for as-
3 sessing civil money penalties, including at a retailer's
4 request a hearing by telephone, or at the nearest re-
5 gional or field office of the Food and Drug Adminis-
6 tration, or at a Federal, State, or county facility
7 within 100 miles from the location of the retail out-
8 let, if such a facility is available.”.

9 (d) SECTION 304.—Section 304 (21 U.S.C. 334) is
10 amended—

11 (1) in subsection (a)(2)—

12 (A) by striking “and” before “(D)”; and

13 (B) by striking “device.” and inserting the
14 following: “device, and (E) Any adulterated or
15 misbranded tobacco product.”;

16 (2) in subsection (d)(1), by inserting “tobacco
17 product,” after “device,”;

18 (3) in subsection (g)(1), by inserting “or to-
19 bacco product” after the term “device” each place
20 such term appears; and

21 (4) in subsection (g)(2)(A), by inserting “or to-
22 bacco product” after “device”.

23 (e) SECTION 505.—Section 505(n)(2) (21 U.S.C.
24 355(n)(2)) is amended by striking “section 904” and in-
25 serting “section 1004”.

1 (f) SECTION 523.—Section 523(b)(2)(D) (21 U.S.C.
2 360m(b)(2)(D)) is amended by striking “section 903(g)”
3 and inserting “section 1003(g)”.

4 (g) SECTION 702.—Section 702(a)(1) (U.S.C.
5 372(a)(1)) is amended—

6 (1) by striking “(a)(1)” and inserting
7 “(a)(1)(A)”; and

8 (2) by adding at the end the following:

9 “(B)(i) For a tobacco product, to the extent feasible,
10 the Secretary shall contract with the States in accordance
11 with this paragraph to carry out inspections of retailers
12 within that State in connection with the enforcement of
13 this Act.

14 “(ii) The Secretary shall not enter into any contract
15 under clause (i) with the government of any of the several
16 States to exercise enforcement authority under this Act
17 on Indian country without the express written consent of
18 the Indian tribe involved.”.

19 (h) SECTION 703.—Section 703 (21 U.S.C. 373) is
20 amended—

21 (1) by inserting “tobacco product,” after the
22 term “device,” each place such term appears; and

23 (2) by inserting “tobacco products,” after the
24 term “devices,” each place such term appears.

1 (i) SECTION 704.—Section 704 (21 U.S.C. 374) is
2 amended—

3 (1) in subsection (a)(1)(A), by inserting “to-
4 bacco products,” after the term “devices,” each
5 place such term appears;

6 (2) in subsection (a)(1)(B), by inserting “or to-
7 bacco products” after the term “restricted devices”
8 each place such term appears;

9 (3) in subsection (b), by inserting “tobacco
10 product,” after “device,”; and

11 (4) in subsection (g)(13), by striking “section
12 903(g)” and inserting “section 1003(g)”.

13 (j) SECTION 705.—Section 705(b) (21 U.S.C.
14 375(b)) is amended by inserting “tobacco products,” after
15 “devices,”.

16 (k) SECTION 709.—Section 709 (21 U.S.C. 379a) is
17 amended by inserting “tobacco product,” after “device,”.

18 (l) SECTION 801.—Section 801 (21 U.S.C. 381) is
19 amended—

20 (1) in subsection (a)—

21 (A) by inserting “tobacco products,” after
22 the term “devices,” ;

23 (B) by inserting “or section 905(h)” after
24 “section 510”; and

1 (C) by striking the term “drugs or de-
2 vices” each time such term appears and insert-
3 ing “drugs, devices, or tobacco products”;

4 (2) in subsection (e)(1), by inserting “tobacco
5 product,” after “device,”; and

6 (3) by adding at the end the following:

7 “(p)(1) Not later than 36 months after the date of
8 enactment of the Family Smoking Prevention and To-
9 bacco Control Act, and annually thereafter, the Secretary
10 shall submit to the Committee on Health, Education,
11 Labor, and Pensions of the Senate and the Committee on
12 Energy and Commerce of the House of Representatives,
13 a report regarding—

14 “(A) the nature, extent, and destination of
15 United States tobacco product exports that do not
16 conform to tobacco product standards established
17 pursuant to this Act;

18 “(B) the public health implications of such ex-
19 ports, including any evidence of a negative public
20 health impact; and

21 “(C) recommendations or assessments of policy
22 alternatives available to Congress and the executive
23 branch to reduce any negative public health impact
24 caused by such exports.

1 “(2) The Secretary is authorized to establish appro-
2 priate information disclosure requirements to carry out
3 this subsection.”.

4 (m) SECTION 1003.—Section 1003(d)(2)(C) (as re-
5 designated by section 101(b)) is amended—

6 (1) by striking “and” after “cosmetics,”; and

7 (2) inserting “, and tobacco products” after
8 “devices”.

9 (n) SECTION 1009.—Section 1009(b) (as redesignig-
10 nated by section 101(b)) is amended by striking “section
11 908” and inserting “section 1008”.

12 (o) SECTION 409 OF THE FEDERAL MEAT INSPEC-
13 TION ACT.—Section 409(a) of the Federal Meat Inspec-
14 tion Act (21 U.S.C. 679(a)) is amended by striking “sec-
15 tion 902(b)” and inserting “section 1002(b)”.

16 (p) RULE OF CONSTRUCTION.—Nothing in this sec-
17 tion is intended or shall be construed to expand, contract,
18 or otherwise modify or amend the existing limitations on
19 State government authority over tribal restricted fee or
20 trust lands.

21 (q) GUIDANCE AND EFFECTIVE DATES.—

22 (1) IN GENERAL.—The Secretary of Health and
23 Human Services shall issue guidance—

24 (A) defining the term “repeated violation”,
25 as used in section 303(f)(8) of the Federal

1 Food, Drug, and Cosmetic Act (21 U.S.C.
2 333(f)(8)) as amended by subsection (c), as in-
3 cluding at least 5 violations of particular re-
4 quirements over a 36-month period at a par-
5 ticular retail outlet that constitute a repeated
6 violation and providing for civil penalties in ac-
7 cordance with paragraph (2);

8 (B) providing for timely and effective no-
9 tice by certified or registered mail or personal
10 delivery to the retailer of each alleged violation
11 at a particular retail outlet prior to conducting
12 a followup compliance check, such notice to be
13 sent to the location specified on the retailer's
14 registration or to the retailer's registered agent
15 if the retailer has provided such agent informa-
16 tion to the Food and Drug Administration prior
17 to the violation;

18 (C) providing for a hearing pursuant to the
19 procedures established through regulations of
20 the Food and Drug Administration for assess-
21 ing civil money penalties, including at a retail-
22 er's request a hearing by telephone or at the
23 nearest regional or field office of the Food and
24 Drug Administration, and providing for an ex-

1 pedited procedure for the administrative appeal
2 of an alleged violation;

3 (D) providing that a person may not be
4 charged with a violation at a particular retail
5 outlet unless the Secretary has provided notice
6 to the retailer of all previous violations at that
7 outlet;

8 (E) establishing that civil money penalties
9 for multiple violations shall increase from one
10 violation to the next violation pursuant to para-
11 graph (2) within the time periods provided for
12 in such paragraph;

13 (F) providing that good faith reliance on
14 the presentation of a false government-issued
15 photographic identification that contains a date
16 of birth does not constitute a violation of any
17 minimum age requirement for the sale of to-
18 bacco products if the retailer has taken effective
19 steps to prevent such violations, including—

20 (i) adopting and enforcing a written
21 policy against sales to minors;

22 (ii) informing its employees of all ap-
23 plicable laws;

24 (iii) establishing disciplinary sanctions
25 for employee noncompliance; and

1 (iv) requiring its employees to verify
2 age by way of photographic identification
3 or electronic scanning device; and

4 (G) providing for the Secretary, in deter-
5 mining whether to impose a no-tobacco-sale
6 order and in determining whether to com-
7 promise, modify, or terminate such an order, to
8 consider whether the retailer has taken effective
9 steps to prevent violations of the minimum age
10 requirements for the sale of tobacco products,
11 including the steps listed in subparagraph (F).

12 (2) PENALTIES FOR VIOLATIONS.—

13 (A) IN GENERAL.—The amount of the civil
14 penalty to be applied for violations of restric-
15 tions promulgated under section 906(d), as de-
16 scribed in paragraph (1), shall be as follows:

17 (i) With respect to a retailer with an
18 approved training program, the amount of
19 the civil penalty shall not exceed—

20 (I) in the case of the first viola-
21 tion, \$0.00 together with the issuance
22 of a warning letter to the retailer;

23 (II) in the case of a second viola-
24 tion within a 12-month period, \$250;

1 (III) in the case of a third viola-
2 tion within a 24-month period, \$500;

3 (IV) in the case of a fourth viola-
4 tion within a 24-month period,
5 \$2,000;

6 (V) in the case of a fifth violation
7 within a 36-month period, \$5,000;
8 and

9 (VI) in the case of a sixth or sub-
10 sequent violation within a 48-month
11 period, \$10,000 as determined by the
12 Secretary on a case-by-case basis.

13 (ii) With respect to a retailer that
14 does not have an approved training pro-
15 gram, the amount of the civil penalty shall
16 not exceed—

17 (I) in the case of the first viola-
18 tion, \$250;

19 (II) in the case of a second viola-
20 tion within a 12-month period, \$500;

21 (III) in the case of a third viola-
22 tion within a 24-month period,
23 \$1,000;

1 (IV) in the case of a fourth viola-
2 tion within a 24-month period,
3 \$2,000;

4 (V) in the case of a fifth violation
5 within a 36-month period, \$5,000;
6 and

7 (VI) in the case of a sixth or sub-
8 sequent violation within a 48-month
9 period, \$10,000 as determined by the
10 Secretary on a case-by-case basis.

11 (B) TRAINING PROGRAM.—For purposes of
12 subparagraph (A), the term “approved training
13 program” means a training program that com-
14 plies with standards developed by the Food and
15 Drug Administration for such programs.

16 (C) CONSIDERATION OF STATE PEN-
17 ALTIES.—The Secretary shall coordinate with
18 the States in enforcing the provisions of this
19 Act and, for purposes of mitigating a civil pen-
20 alty to be applied for a violation by a retailer
21 of any restriction promulgated under section
22 906(d), shall consider the amount of any pen-
23 alties paid by the retailer to a State for the
24 same violation.

1 (3) GENERAL EFFECTIVE DATE.—The amend-
2 ments made by paragraphs (2), (3), and (4) of sub-
3 section (c) shall take effect upon the issuance of
4 guidance described in paragraph (1) of this sub-
5 section.

6 (4) SPECIAL EFFECTIVE DATE.—The amend-
7 ment made by subsection (c)(1) shall take effect on
8 the date of enactment of this Act.

9 (5) PACKAGE LABEL REQUIREMENTS.—The
10 package label requirements of paragraphs (2), (3),
11 and (4) of section 903(a) of the Federal Food,
12 Drug, and Cosmetic Act (as amended by this Act)
13 shall take effect on the date that is 12 months after
14 the date of enactment of this Act. The effective date
15 shall be with respect to the date of manufacture,
16 provided that, in any case, beginning 30 days after
17 such effective date, a manufacturer shall not intro-
18 duce into the domestic commerce of the United
19 States any product, irrespective of the date of manu-
20 facture, that is not in conformance with section
21 903(a)(2), (3), and (4) and section 920(a) of the
22 Federal Food, Drug, and Cosmetic Act.

23 (6) ADVERTISING REQUIREMENTS.—The adver-
24 tising requirements of section 903(a)(8) of the Fed-
25 eral Food, Drug, and Cosmetic Act (as amended by

1 this Act) shall take effect on the date that is 12
2 months after the date of enactment of this Act.

3 **SEC. 104. STUDY ON RAISING THE MINIMUM AGE TO PUR-**
4 **CHASE TOBACCO PRODUCTS.**

5 The Secretary of Health and Human Services shall—

6 (1) convene an expert panel to conduct a study
7 on the public health implications of raising the min-
8 imum age to purchase tobacco products; and

9 (2) not later than 5 years after the date of en-
10 actment of this Act, submit a report to the Congress
11 on the results of such study.

12 **SEC. 105. ENFORCEMENT ACTION PLAN FOR ADVERTISING**
13 **AND PROMOTION RESTRICTIONS.**

14 (a) ACTION PLAN.—

15 (1) DEVELOPMENT.—Not later than 6 months
16 after the date of enactment of this Act, the Sec-
17 retary of Health and Human Services (in this sec-
18 tion referred to as the “Secretary”) shall develop
19 and publish an action plan to enforce restrictions
20 adopted pursuant to section 906 of the Federal
21 Food, Drug, and Cosmetic Act, as added by section
22 101(b) of this Act, or pursuant to section 102(a) of
23 this Act, on promotion and advertising of menthol
24 and other cigarettes to youth.

1 (2) CONSULTATION.—The action plan required
2 by paragraph (1) shall be developed in consultation
3 with public health organizations and other stake-
4 holders with demonstrated expertise and experience
5 in serving minority communities.

6 (3) PRIORITY.—The action plan required by
7 paragraph (1) shall include provisions designed to
8 ensure enforcement of the restrictions described in
9 paragraph (1) in minority communities.

10 (b) STATE AND LOCAL ACTIVITIES.—

11 (1) INFORMATION ON AUTHORITY.—Not later
12 than 3 months after the date of enactment of this
13 Act, the Secretary shall inform State, local, and trib-
14 al governments of the authority provided to such en-
15 tities under section 5(c) of the Federal Cigarette La-
16 beling and Advertising Act, as added by section 203
17 of this Act, or preserved by such entities under sec-
18 tion 916 of the Federal Food, Drug, and Cosmetic
19 Act, as added by section 101(b) of this Act.

20 (2) COMMUNITY ASSISTANCE.—At the request
21 of communities seeking assistance to prevent under-
22 age tobacco use, the Secretary shall provide such as-
23 sistance, including assistance with strategies to ad-
24 dress the prevention of underage tobacco use in com-

1 munities with a disproportionate use of menthol
2 cigarettes by minors.

3 **TITLE II—TOBACCO PRODUCT**
4 **WARNINGS; CONSTITUENT**
5 **AND SMOKE CONSTITUENT**
6 **DISCLOSURE**

7 **SEC. 201. CIGARETTE LABEL AND ADVERTISING WARNINGS.**

8 (a) AMENDMENT.—Section 4 of the Federal Ciga-
9 rette Labeling and Advertising Act (15 U.S.C. 1333) is
10 amended to read as follows:

11 **“SEC. 4. LABELING.**

12 “(a) LABEL REQUIREMENTS.—

13 “(1) IN GENERAL.—It shall be unlawful for any
14 person to manufacture, package, sell, offer to sell,
15 distribute, or import for sale or distribution within
16 the United States any cigarettes the package of
17 which fails to bear, in accordance with the require-
18 ments of this section, one of the following labels:

19 “WARNING: Cigarettes are addictive.

20 “WARNING: Tobacco smoke can harm
21 your children.

22 “WARNING: Cigarettes cause fatal lung
23 disease.

24 “WARNING: Cigarettes cause cancer.

1 “WARNING: Cigarettes cause strokes and
2 heart disease.

3 “WARNING: Smoking during pregnancy
4 can harm your baby.

5 “WARNING: Smoking can kill you.

6 “WARNING: Tobacco smoke causes fatal
7 lung disease in nonsmokers.

8 “WARNING: Quitting smoking now great-
9 ly reduces serious risks to your health.

10 “(2) PLACEMENT; TYPOGRAPHY; ETC.—Each
11 label statement required by paragraph (1) shall be
12 located in the upper portion of the front and rear
13 panels of the package, directly on the package un-
14 derneath the cellophane or other clear wrapping.
15 Each label statement shall comprise at least the top
16 30 percent of the front and rear panels of the pack-
17 age. The word ‘WARNING’ shall appear in capital
18 letters and all text shall be in conspicuous and leg-
19 ible 17-point type, unless the text of the label state-
20 ment would occupy more than 70 percent of such
21 area, in which case the text may be in a smaller con-
22 spicuous and legible type size, provided that at least
23 60 percent of such area is occupied by required text.
24 The text shall be black on a white background, or
25 white on a black background, in a manner that con-

1 trasts, by typography, layout, or color, with all other
2 printed material on the package, in an alternating
3 fashion under the plan submitted under subsection
4 (c).

5 “(3) DOES NOT APPLY TO FOREIGN DISTRIBUTION.—The provisions of this subsection do not
6 apply to a tobacco product manufacturer or distributor of cigarettes which does not manufacture,
7 package, or import cigarettes for sale or distribution
8 within the United States.

11 “(4) APPLICABILITY TO RETAILERS.—A retailer
12 of cigarettes shall not be in violation of this subsection for packaging that—

14 “(A) contains a warning label;

15 “(B) is supplied to the retailer by a
16 license- or permit-holding tobacco product manufacturer, importer, or distributor; and

18 “(C) is not altered by the retailer in a way
19 that is material to the requirements of this subsection.
20

21 “(b) ADVERTISING REQUIREMENTS.—

22 “(1) IN GENERAL.—It shall be unlawful for any
23 tobacco product manufacturer, importer, distributor,
24 or retailer of cigarettes to advertise or cause to be
25 advertised within the United States any cigarette

1 unless its advertising bears, in accordance with the
2 requirements of this section, one of the labels speci-
3 fied in subsection (a).

4 “(2) TYPOGRAPHY, ETC.—Each label statement
5 required by subsection (a) in cigarette advertising
6 shall comply with the standards set forth in this
7 paragraph. For press and poster advertisements,
8 each such statement and (where applicable) any re-
9 quired statement relating to tar, nicotine, or other
10 constituent (including a smoke constituent) yield
11 shall comprise at least 20 percent of the area of the
12 advertisement and shall appear in a conspicuous and
13 prominent format and location at the top of each ad-
14 vertisement within the trim area. The Secretary may
15 revise the required type sizes in such area in such
16 manner as the Secretary determines appropriate.
17 The word ‘WARNING’ shall appear in capital let-
18 ters, and each label statement shall appear in con-
19 spicuous and legible type. The text of the label state-
20 ment shall be black if the background is white and
21 white if the background is black, under the plan sub-
22 mitted under subsection (c). The label statements
23 shall be enclosed by a rectangular border that is the
24 same color as the letters of the statements and that
25 is the width of the first downstroke of the capital

1 ‘W’ of the word ‘WARNING’ in the label state-
2 ments. The text of such label statements shall be in
3 a typeface pro rata to the following requirements:
4 45-point type for a whole-page broadsheet newspaper
5 advertisement; 39-point type for a half-page
6 broadsheet newspaper advertisement; 39-point type
7 for a whole-page tabloid newspaper advertisement;
8 27-point type for a half-page tabloid newspaper ad-
9 vertisement; 31.5-point type for a double page
10 spread magazine or whole-page magazine advertise-
11 ment; 22.5-point type for a 28 centimeter by 3 col-
12 umn advertisement; and 15-point type for a 20 cen-
13 timeter by 2 column advertisement. The label state-
14 ments shall be in English, except that—

15 “(A) in the case of an advertisement that
16 appears in a newspaper, magazine, periodical,
17 or other publication that is not in English, the
18 statements shall appear in the predominant lan-
19 guage of the publication; and

20 “(B) in the case of any other advertise-
21 ment that is not in English, the statements
22 shall appear in the same language as that prin-
23 cipally used in the advertisement.

24 “(3) MATCHBOOKS.—Notwithstanding para-
25 graph (2), for matchbooks (defined as containing not

1 more than 20 matches) customarily given away with
2 the purchase of tobacco products, each label state-
3 ment required by subsection (a) may be printed on
4 the inside cover of the matchbook.

5 “(4) ADJUSTMENT BY SECRETARY.—The Sec-
6 retary may, through a rulemaking under section 553
7 of title 5, United States Code, adjust the format and
8 type sizes for the label statements required by this
9 section; the text, format, and type sizes of any re-
10 quired tar, nicotine yield, or other constituent (in-
11 cluding smoke constituent) disclosures; or the text,
12 format, and type sizes for any other disclosures re-
13 quired under the Federal Food, Drug, and Cosmetic
14 Act. The text of any such label statements or disclo-
15 sures shall be required to appear only within the 20
16 percent area of cigarette advertisements provided by
17 paragraph (2). The Secretary shall promulgate regu-
18 lations which provide for adjustments in the format
19 and type sizes of any text required to appear in such
20 area to ensure that the total text required to appear
21 by law will fit within such area.

22 “(c) MARKETING REQUIREMENTS.—

23 “(1) RANDOM DISPLAY.—The label statements
24 specified in subsection (a)(1) shall be randomly dis-
25 played in each 12-month period, in as equal a num-

1 ber of times as is possible on each brand of the
2 product and be randomly distributed in all areas of
3 the United States in which the product is marketed
4 in accordance with a plan submitted by the tobacco
5 product manufacturer, importer, distributor, or re-
6 tailer and approved by the Secretary.

7 “(2) ROTATION.—The label statements speci-
8 fied in subsection (a)(1) shall be rotated quarterly in
9 alternating sequence in advertisements for each
10 brand of cigarettes in accordance with a plan sub-
11 mitted by the tobacco product manufacturer, im-
12 porter, distributor, or retailer to, and approved by,
13 the Secretary.

14 “(3) REVIEW.—The Secretary shall review each
15 plan submitted under paragraph (2) and approve it
16 if the plan—

17 “(A) will provide for the equal distribution
18 and display on packaging and the rotation re-
19 quired in advertising under this subsection; and

20 “(B) assures that all of the labels required
21 under this section will be displayed by the to-
22 bacco product manufacturer, importer, dis-
23 tributor, or retailer at the same time.

24 “(4) APPLICABILITY TO RETAILERS.—This sub-
25 section and subsection (b) apply to a retailer only if

1 that retailer is responsible for or directs the label
2 statements required under this section except that
3 this paragraph shall not relieve a retailer of liability
4 if the retailer displays, in a location open to the pub-
5 lic, an advertisement that does not contain a warn-
6 ing label or has been altered by the retailer in a way
7 that is material to the requirements of this sub-
8 section and subsection (b).”.

9 (b) **EFFECTIVE DATE.**—The amendment made by
10 subsection (a) shall take effect 12 months after the date
11 of enactment of this Act. Such effective date shall be with
12 respect to the date of manufacture, provided that, in any
13 case, beginning 30 days after such effective date, a manu-
14 facturer shall not introduce into the domestic commerce
15 of the United States any product, irrespective of the date
16 of manufacture, that is not in conformance with section
17 4 of the Federal Cigarette Labeling and Advertising Act
18 (15 U.S.C. 1333), as amended by subsection (a).

19 **SEC. 202. AUTHORITY TO REVISE CIGARETTE WARNING**
20 **LABEL STATEMENTS.**

21 (a) **PREEMPTION.**—Section 5(a) of the Federal Ciga-
22 rette Labeling and Advertising Act (15 U.S.C. 1334(a))
23 is amended by striking “No” and inserting “Except to the
24 extent the Secretary requires additional or different state-
25 ments on any cigarette package by a regulation, by an

1 order, by a standard, by an authorization to market a
2 product, or by a condition of marketing a product, pursu-
3 ant to the Family Smoking Prevention and Tobacco Con-
4 trol Act (and the amendments made by that Act), or as
5 required under section 903(a)(2) or section 920(a) of the
6 Federal Food, Drug, and Cosmetic Act, no”.

7 (b) CHANGE IN REQUIRED STATEMENTS.—Section 4
8 of the Federal Cigarette Labeling and Advertising Act (15
9 U.S.C. 1333), as amended by section 201, is further
10 amended by adding at the end the following:

11 “(d) CHANGE IN REQUIRED STATEMENTS.—The
12 Secretary may, by a rulemaking conducted under section
13 553 of title 5, United States Code, adjust the format, type
14 size, and text of any of the label requirements, require
15 color graphics to accompany the text, increase the re-
16 quired label area from 30 percent up to 50 percent of the
17 front and rear panels of the package, or establish the for-
18 mat, type size, and text of any other disclosures required
19 under the Federal Food, Drug, and Cosmetic Act, if the
20 Secretary finds that such a change would promote greater
21 public understanding of the risks associated with the use
22 of tobacco products.”.

1 **SEC. 203. STATE REGULATION OF CIGARETTE ADVER-**
2 **TISING AND PROMOTION.**

3 Section 5 of the Federal Cigarette Labeling and Ad-
4 vertising Act (15 U.S.C. 1334) is amended by adding at
5 the end the following:

6 “(c) EXCEPTION.—Notwithstanding subsection (b), a
7 State or locality may enact statutes and promulgate regu-
8 lations, based on smoking and health, that take effect
9 after the effective date of the Family Smoking Prevention
10 and Tobacco Control Act, imposing specific bans or re-
11 strictions on the time, place, and manner, but not content,
12 of the advertising or promotion of any cigarettes.”.

13 **SEC. 204. SMOKELESS TOBACCO LABELS AND ADVERTISING**
14 **WARNINGS.**

15 (a) AMENDMENT.—Section 3 of the Comprehensive
16 Smokeless Tobacco Health Education Act of 1986 (15
17 U.S.C. 4402) is amended to read as follows:

18 **“SEC. 3. SMOKELESS TOBACCO WARNING.**

19 “(a) GENERAL RULE.—

20 “(1) It shall be unlawful for any person to man-
21 ufacture, package, sell, offer to sell, distribute, or
22 import for sale or distribution within the United
23 States any smokeless tobacco product unless the
24 product package bears, in accordance with the re-
25 quirements of this Act, one of the following labels:

1 “WARNING: This product can cause
2 mouth cancer.

3 “WARNING: This product can cause gum
4 disease and tooth loss.

5 “WARNING: This product is not a safe al-
6 ternative to cigarettes.

7 “WARNING: Smokeless tobacco is addict-
8 ive.

9 “(2) Each label statement required by para-
10 graph (1) shall be—

11 “(A) located on the 2 principal display
12 panels of the package, and each label statement
13 shall comprise at least 30 percent of each such
14 display panel; and

15 “(B) in 17-point conspicuous and legible
16 type and in black text on a white background,
17 or white text on a black background, in a man-
18 ner that contrasts by typography, layout, or
19 color, with all other printed material on the
20 package, in an alternating fashion under the
21 plan submitted under subsection (b)(3), except
22 that if the text of a label statement would oc-
23 cupy more than 70 percent of the area specified
24 by subparagraph (A), such text may appear in
25 a smaller type size, so long as at least 60 per-

1 cent of such warning area is occupied by the
2 label statement.

3 “(3) The label statements required by para-
4 graph (1) shall be introduced by each tobacco prod-
5 uct manufacturer, packager, importer, distributor, or
6 retailer of smokeless tobacco products concurrently
7 into the distribution chain of such products.

8 “(4) The provisions of this subsection do not
9 apply to a tobacco product manufacturer or dis-
10 tributor of any smokeless tobacco product that does
11 not manufacture, package, or import smokeless to-
12 bacco products for sale or distribution within the
13 United States.

14 “(5) A retailer of smokeless tobacco products
15 shall not be in violation of this subsection for pack-
16 aging that—

17 “(A) contains a warning label;

18 “(B) is supplied to the retailer by a
19 license- or permit-holding tobacco product man-
20 ufacturer, importer, or distributor; and

21 “(C) is not altered by the retailer in a way
22 that is material to the requirements of this sub-
23 section.

24 “(b) REQUIRED LABELS.—

1 “(1) It shall be unlawful for any tobacco prod-
2 uct manufacturer, packager, importer, distributor, or
3 retailer of smokeless tobacco products to advertise or
4 cause to be advertised within the United States any
5 smokeless tobacco product unless its advertising
6 bears, in accordance with the requirements of this
7 section, one of the labels specified in subsection (a).

8 “(2)(A) Each label statement required by sub-
9 section (a) in smokeless tobacco advertising shall
10 comply with the standards set forth in this para-
11 graph.

12 “(B) For press and poster advertisements, each
13 such statement and (where applicable) any required
14 statement relating to tar, nicotine, or other con-
15 stituent yield shall comprise at least 20 percent of
16 the area of the advertisement.

17 “(C) The word ‘WARNING’ shall appear in
18 capital letters, and each label statement shall appear
19 in conspicuous and legible type.

20 “(D) The text of the label statement shall be
21 black on a white background, or white on a black
22 background, in an alternating fashion under the
23 plan submitted under paragraph (3).

24 “(E) The label statements shall be enclosed by
25 a rectangular border that is the same color as the

1 letters of the statements and that is the width of the
2 first downstroke of the capital ‘W’ of the word
3 ‘WARNING’ in the label statements.

4 “(F) The text of such label statements shall be
5 in a typeface pro rata to the following requirements:
6 45-point type for a whole-page broadsheet newspaper
7 advertisement; 39-point type for a half-page
8 broadsheet newspaper advertisement; 39-point type
9 for a whole-page tabloid newspaper advertisement;
10 27-point type for a half-page tabloid newspaper ad-
11 vertisement; 31.5-point type for a double page
12 spread magazine or whole-page magazine advertise-
13 ment; 22.5-point type for a 28 centimeter by 3 col-
14 umn advertisement; and 15-point type for a 20 cen-
15 timeter by 2 column advertisement.

16 “(G) The label statements shall be in English,
17 except that—

18 “(i) in the case of an advertisement that
19 appears in a newspaper, magazine, periodical,
20 or other publication that is not in English, the
21 statements shall appear in the predominant lan-
22 guage of the publication; and

23 “(ii) in the case of any other advertisement
24 that is not in English, the statements shall ap-

1 pear in the same language as that principally
2 used in the advertisement.

3 “(3)(A) The label statements specified in sub-
4 section (a)(1) shall be randomly displayed in each
5 12-month period, in as equal a number of times as
6 is possible on each brand of the product and be ran-
7 domly distributed in all areas of the United States
8 in which the product is marketed in accordance with
9 a plan submitted by the tobacco product manufac-
10 turer, importer, distributor, or retailer and approved
11 by the Secretary.

12 “(B) The label statements specified in sub-
13 section (a)(1) shall be rotated quarterly in alter-
14 nating sequence in advertisements for each brand of
15 smokeless tobacco product in accordance with a plan
16 submitted by the tobacco product manufacturer, im-
17 porter, distributor, or retailer to, and approved by,
18 the Secretary.

19 “(C) The Secretary shall review each plan sub-
20 mitted under subparagraphs (A) and (B) and ap-
21 prove it if the plan—

22 “(i) will provide for the equal distribution
23 and display on packaging and the rotation re-
24 quired in advertising under this subsection; and

1 “(ii) assures that all of the labels required
2 under this section will be displayed by the to-
3 bacco product manufacturer, importer, dis-
4 tributor, or retailer at the same time.

5 “(D) This paragraph applies to a retailer only
6 if that retailer is responsible for or directs the label
7 statements under this section, unless the retailer dis-
8 plays, in a location open to the public, an advertise-
9 ment that does not contain a warning label or has
10 been altered by the retailer in a way that is material
11 to the requirements of this subsection.

12 “(4) The Secretary may, through a rulemaking
13 under section 553 of title 5, United States Code, ad-
14 just the format and type sizes for the label state-
15 ments required by this section; the text, format, and
16 type sizes of any required tar, nicotine yield, or
17 other constituent disclosures; or the text, format,
18 and type sizes for any other disclosures required
19 under the Federal Food, Drug, and Cosmetic Act.
20 The text of any such label statements or disclosures
21 shall be required to appear only within the 20 per-
22 cent area of advertisements provided by paragraph
23 (2). The Secretary shall promulgate regulations
24 which provide for adjustments in the format and
25 type sizes of any text required to appear in such

1 area to ensure that the total text required to appear
2 by law will fit within such area.

3 “(c) TELEVISION AND RADIO ADVERTISING.—It is
4 unlawful to advertise smokeless tobacco on any medium
5 of electronic communications subject to the jurisdiction of
6 the Federal Communications Commission.”.

7 (b) EFFECTIVE DATE.—The amendment made by
8 subsection (a) shall take effect 12 months after the date
9 of enactment of this Act. Such effective date shall be with
10 respect to the date of manufacture, provided that, in any
11 case, beginning 30 days after such effective date, a manu-
12 facturer shall not introduce into the domestic commerce
13 of the United States any product, irrespective of the date
14 of manufacture, that is not in conformance with section
15 3 of the Comprehensive Smokeless Tobacco Health Edu-
16 cation Act of 1986 (15 U.S.C. 4402), as amended by sub-
17 section (a)

18 **SEC. 205. AUTHORITY TO REVISE SMOKELESS TOBACCO**
19 **PRODUCT WARNING LABEL STATEMENTS.**

20 (a) IN GENERAL.—Section 3 of the Comprehensive
21 Smokeless Tobacco Health Education Act of 1986 (15
22 U.S.C. 4402), as amended by section 204, is further
23 amended by adding at the end the following:

24 “(d) AUTHORITY TO REVISE WARNING LABEL
25 STATEMENTS.—The Secretary may, by a rulemaking con-

1 ducted under section 553 of title 5, United States Code,
2 adjust the format, type size, and text of any of the label
3 requirements, require color graphics to accompany the
4 text, increase the required label area from 30 percent up
5 to 50 percent of the front and rear panels of the package,
6 or establish the format, type size, and text of any other
7 disclosures required under the Federal Food, Drug, and
8 Cosmetic Act, if the Secretary finds that such a change
9 would promote greater public understanding of the risks
10 associated with the use of smokeless tobacco products.”.

11 (b) PREEMPTION.—Section 7(a) of the Comprehen-
12 sive Smokeless Tobacco Health Education Act of 1986 (15
13 U.S.C. 4406(a)) is amended by striking “No” and insert-
14 ing “Except as provided in the Family Smoking Preven-
15 tion and Tobacco Control Act (and the amendments made
16 by that Act), no”.

17 **SEC. 206. TAR, NICOTINE, AND OTHER SMOKE CON-**
18 **STITUENT DISCLOSURE TO THE PUBLIC.**

19 Section 4 of the Federal Cigarette Labeling and Ad-
20 vertising Act (15 U.S.C. 1333), as amended by sections
21 201 and 202, is further amended by adding at the end
22 the following:

23 “(e) TAR, NICOTINE, AND OTHER SMOKE CON-
24 STITUENT DISCLOSURE.—

1 “(1) IN GENERAL.—The Secretary shall, by a
2 rulemaking conducted under section 553 of title 5,
3 United States Code, determine (in the Secretary’s
4 sole discretion) whether cigarette and other tobacco
5 product manufacturers shall be required to include
6 in the area of each cigarette advertisement specified
7 by subsection (b) of this section, or on the package
8 label, or both, the tar and nicotine yields of the ad-
9 vertised or packaged brand. Any such disclosure
10 shall be in accordance with the methodology estab-
11 lished under such regulations, shall conform to the
12 type size requirements of subsection (b) of this sec-
13 tion, and shall appear within the area specified in
14 subsection (b) of this section.

15 “(2) RESOLUTION OF DIFFERENCES.—Any dif-
16 ferences between the requirements established by the
17 Secretary under paragraph (1) and tar and nicotine
18 yield reporting requirements established by the Fed-
19 eral Trade Commission shall be resolved by a memo-
20 randum of understanding between the Secretary and
21 the Federal Trade Commission.

22 “(3) CIGARETTE AND OTHER TOBACCO PROD-
23 UCT CONSTITUENTS.—In addition to the disclosures
24 required by paragraph (1), the Secretary may, under
25 a rulemaking conducted under section 553 of title 5,

1 United States Code, prescribe disclosure require-
2 ments regarding the level of any cigarette or other
3 tobacco product constituent including any smoke
4 constituent. Any such disclosure may be required if
5 the Secretary determines that disclosure would be of
6 benefit to the public health, or otherwise would in-
7 crease consumer awareness of the health con-
8 sequences of the use of tobacco products, except that
9 no such prescribed disclosure shall be required on
10 the face of any cigarette package or advertisement.
11 Nothing in this section shall prohibit the Secretary
12 from requiring such prescribed disclosure through a
13 cigarette or other tobacco product package or adver-
14 tisement insert, or by any other means under the
15 Federal Food, Drug, and Cosmetic Act.

16 “(4) RETAILERS.—This subsection applies to a
17 retailer only if that retailer is responsible for or di-
18 rects the label statements required under this sec-
19 tion.”.

1 **TITLE III—PREVENTION OF IL-**
2 **LICIT TRADE IN TOBACCO**
3 **PRODUCTS**

4 **SEC. 301. LABELING, RECORDKEEPING, RECORDS INSPEC-**
5 **TION.**

6 Chapter IX of the Federal Food, Drug, and Cosmetic
7 Act, as added by section 101, is further amended by add-
8 ing at the end the following:

9 **“SEC. 920. LABELING, RECORDKEEPING, RECORDS INSPEC-**
10 **TION.**

11 “(a) ORIGIN LABELING.—

12 “(1) REQUIREMENT.—Beginning 1 year after
13 the date of enactment of the Family Smoking Pre-
14 vention and Tobacco Control Act, the label, pack-
15 aging, and shipping containers of tobacco products
16 for introduction or delivery for introduction into
17 interstate commerce in the United States shall bear
18 the statement ‘sale only allowed in the United
19 States’.

20 “(2) EFFECTIVE DATE.—The effective date
21 specified in paragraph (1) shall be with respect to
22 the date of manufacture, provided that, in any case,
23 beginning 30 days after such effective date, a manu-
24 facturer shall not introduce into the domestic com-
25 merce of the United States any product, irrespective

1 of the date of manufacture, that is not in conform-
2 ance with such paragraph.

3 “(b) REGULATIONS CONCERNING RECORDKEEPING
4 FOR TRACKING AND TRACING.—

5 “(1) IN GENERAL.—The Secretary shall pro-
6 mulgate regulations regarding the establishment and
7 maintenance of records by any person who manufac-
8 tures, processes, transports, distributes, receives,
9 packages, holds, exports, or imports tobacco prod-
10 ucts.

11 “(2) INSPECTION.—In promulgating the regula-
12 tions described in paragraph (1), the Secretary shall
13 consider which records are needed for inspection to
14 monitor the movement of tobacco products from the
15 point of manufacture through distribution to retail
16 outlets to assist in investigating potential illicit
17 trade, smuggling, or counterfeiting of tobacco prod-
18 ucts.

19 “(3) CODES.—The Secretary may require codes
20 on the labels of tobacco products or other designs or
21 devices for the purpose of tracking or tracing the to-
22 bacco product through the distribution system.

23 “(4) SIZE OF BUSINESS.—The Secretary shall
24 take into account the size of a business in promul-
25 gating regulations under this section.

1 “(5) RECORDKEEPING BY RETAILERS.—The
2 Secretary shall not require any retailer to maintain
3 records relating to individual purchasers of tobacco
4 products for personal consumption.

5 “(c) RECORDS INSPECTION.—If the Secretary has a
6 reasonable belief that a tobacco product is part of an illicit
7 trade or smuggling or is a counterfeit product, each person
8 who manufactures, processes, transports, distributes, re-
9 ceives, holds, packages, exports, or imports tobacco prod-
10 ucts shall, at the request of an officer or employee duly
11 designated by the Secretary, permit such officer or em-
12 ployee, at reasonable times and within reasonable limits
13 and in a reasonable manner, upon the presentation of ap-
14 propriate credentials and a written notice to such person,
15 to have access to and copy all records (including financial
16 records) relating to such article that are needed to assist
17 the Secretary in investigating potential illicit trade, smug-
18 gling, or counterfeiting of tobacco products. The Secretary
19 shall not authorize an officer or employee of the govern-
20 ment of any of the several States to exercise authority
21 under the preceding sentence on Indian country without
22 the express written consent of the Indian tribe involved.

23 “(d) KNOWLEDGE OF ILLEGAL TRANSACTION.—

24 “(1) NOTIFICATION.—If the manufacturer or
25 distributor of a tobacco product has knowledge

1 which reasonably supports the conclusion that a to-
2 bacco product manufactured or distributed by such
3 manufacturer or distributor that has left the control
4 of such person may be or has been—

5 “(A) imported, exported, distributed, or of-
6 ferred for sale in interstate commerce by a per-
7 son without paying duties or taxes required by
8 law; or

9 “(B) imported, exported, distributed, or di-
10 verted for possible illicit marketing,
11 the manufacturer or distributor shall promptly no-
12 tify the Attorney General and the Secretary of the
13 Treasury of such knowledge.

14 “(2) KNOWLEDGE DEFINED.—For purposes of
15 this subsection, the term ‘knowledge’ as applied to
16 a manufacturer or distributor means—

17 “(A) the actual knowledge that the manu-
18 facturer or distributor had; or

19 “(B) the knowledge which a reasonable
20 person would have had under like circumstances
21 or which would have been obtained upon the ex-
22 ercise of due care.”.

1 **SEC. 302. STUDY AND REPORT.**

2 (a) STUDY.—The Comptroller General of the United
3 States shall conduct a study of cross-border trade in to-
4 bacco products to—

5 (1) collect data on cross-border trade in tobacco
6 products, including illicit trade and trade of counter-
7 feit tobacco products and make recommendations on
8 the monitoring of such trade;

9 (2) collect data on cross-border advertising (any
10 advertising intended to be broadcast, transmitted, or
11 distributed from the United States to another coun-
12 try) of tobacco products and make recommendations
13 on how to prevent or eliminate, and what tech-
14 nologies could help facilitate the elimination of,
15 cross-border advertising; and

16 (3) collect data on the health effects (particu-
17 larly with respect to individuals under 18 years of
18 age) resulting from cross-border trade in tobacco
19 products, including the health effects resulting
20 from—

21 (A) the illicit trade of tobacco products
22 and the trade of counterfeit tobacco products;
23 and

24 (B) the differing tax rates applicable to to-
25 bacco products.

1 (b) REPORT.—Not later than 18 months after the
2 date of enactment of this Act, the Comptroller General
3 of the United States shall submit to the Committee on
4 Health, Education, Labor, and Pensions of the Senate and
5 the Committee on Energy and Commerce of the House
6 of Representatives a report on the study described in sub-
7 section (a).

8 (c) DEFINITION.—In this section:

9 (1) The term “cross-border trade” means trade
10 across a border of the United States, a State or Ter-
11 ritory, or Indian country.

12 (2) The term “Indian country” has the mean-
13 ing given to such term in section 1151 of title 18,
14 United States Code.

15 (3) The terms “State” and “Territory” have
16 the meanings given to those terms in section 201 of
17 the Federal Food, Drug, and Cosmetic Act (21
18 U.S.C. 321).

19 **TITLE IV—THRIFT SAVINGS** 20 **PLAN ENHANCEMENT**

21 **SEC. 401. SHORT TITLE.**

22 This title may be cited as the “Thrift Savings Plan
23 Enhancement Act of 2009”.

1 **SEC. 402. AUTOMATIC ENROLLMENTS.**

2 (a) IN GENERAL.—Section 8432(b) of title 5, United
3 States Code, is amended by striking paragraphs (2)
4 through (4) and inserting the following:

5 “(2)(A) The Board shall by regulation provide for an
6 eligible individual to be automatically enrolled to make
7 contributions under subsection (a) at the default percent-
8 age of basic pay.

9 “(B) For purposes of this paragraph, the default per-
10 centage shall be equal to 3 percent or such other percent-
11 age, not less than 2 percent nor more than 5 percent, as
12 the Board may by regulation prescribe.

13 “(C) The regulations shall include provisions under
14 which any individual who would otherwise be automatically
15 enrolled in accordance with subparagraph (A) may—

16 “(i) modify the percentage or amount to be con-
17 tributed pursuant to automatic enrollment, effective
18 from the start of such enrollment; or

19 “(ii) decline automatic enrollment altogether.

20 “(D) For purposes of this paragraph, the term ‘eligi-
21 ble individual’ means any individual who, after any regula-
22 tions under subparagraph (A) first take effect, is ap-
23 pointed, transferred, or reappointed to a position in which
24 that individual is eligible to contribute to the Thrift Sav-
25 ings Fund.

1 “(E) Sections 8351(a)(1), 8440a(a)(1), 8440b(a)(1),
2 8440c(a)(1), 8440d(a)(1), and 8440e(a)(1) shall be ap-
3 plied in a manner consistent with the purposes of this
4 paragraph.”.

5 (b) TECHNICAL AMENDMENT.—Section 8432(b)(1)
6 of title 5, United States Code, is amended by striking the
7 parenthetical matter in subparagraph (B).

8 **SEC. 403. QUALIFIED ROTH CONTRIBUTION PROGRAM.**

9 (a) IN GENERAL.—Subchapter III of chapter 84 of
10 title 5, United States Code, is amended by inserting after
11 section 8432c the following:

12 **“§ 8432d. Qualified Roth contribution program**

13 “(a) DEFINITIONS.—For purposes of this section—

14 “(1) the term ‘qualified Roth contribution pro-
15 gram’ means a program described in paragraph (1)
16 of section 402A(b) of the Internal Revenue Code of
17 1986 which meets the requirements of paragraph (2)
18 of such section; and

19 “(2) the terms ‘designated Roth contribution’
20 and ‘elective deferral’ have the meanings given such
21 terms in section 402A of the Internal Revenue Code
22 of 1986.

23 “(b) AUTHORITY TO ESTABLISH.—The Board shall
24 by regulation provide for the inclusion in the Thrift Sav-

1 ings Plan of a qualified Roth contribution program, under
2 such terms and conditions as the Board may prescribe.

3 “(c) REQUIRED PROVISIONS.—The regulations under
4 subsection (b) shall include—

5 “(1) provisions under which an election to make
6 designated Roth contributions may be made—

7 “(A) by any individual who is eligible to
8 make contributions under section 8351,
9 8432(a), 8440a, 8440b, 8440c, 8440d, or
10 8440e; and

11 “(B) by any individual, not described in
12 subparagraph (A), who is otherwise eligible to
13 make elective deferrals under the Thrift Sav-
14 ings Plan;

15 “(2) any provisions which may, as a result of
16 enactment of this section, be necessary in order to
17 clarify the meaning of any reference to an ‘account’
18 made in section 8432(f), 8433, 8434(d), 8435,
19 8437, or any other provision of law; and

20 “(3) any other provisions which may be nec-
21 essary to carry out this section.”.

22 (b) CLERICAL AMENDMENT.—The analysis for chap-
23 ter 84 of title 5, United States Code, is amended by insert-
24 ing after the item relating to section 8432c the following:

“8432d. Qualified Roth contribution program.”.

1 **SEC. 404. AUTHORITY TO ESTABLISH SELF-DIRECTED IN-**
2 **VESTMENT WINDOW.**

3 (a) IN GENERAL.—Section 8438(b)(1) of title 5,
4 United States Code, is amended—

5 (1) in subparagraph (D), by striking “and” at
6 the end;

7 (2) in subparagraph (E), by striking the period
8 and inserting “; and”; and

9 (3) by adding after subparagraph (E) the fol-
10 lowing:

11 “(F) a self-directed investment window, if
12 the Board authorizes such window under para-
13 graph (5).”.

14 (b) REQUIREMENTS.—Section 8438(b) of title 5,
15 United States Code, is amended by adding at the end the
16 following:

17 “(5)(A) The Board may authorize the addition of a
18 self-directed investment window under the Thrift Savings
19 Plan if the Board determines that such addition would be
20 in the best interests of participants.

21 “(B) The self-directed investment window shall be
22 limited to—

23 “(i) low-cost, passively-managed index funds
24 that offer diversification benefits; and

1 “(ii) other investment options, if the Board de-
2 termines the options to be appropriate retirement in-
3 vestment vehicles for participants.

4 “(C) The Board shall ensure that any administrative
5 expenses related to use of the self-directed investment win-
6 dow are borne solely by the participants who use such win-
7 dow.

8 “(D) The Board may establish such other terms and
9 conditions for the self-directed investment window as the
10 Board considers appropriate to protect the interests of
11 participants, including requirements relating to risk dis-
12 closure.

13 “(E) The Board shall consult with the Employee
14 Thrift Advisory Council (established under section 8473)
15 before establishing any self-directed investment window.”.

16 **SEC. 405. REPORTING REQUIREMENTS.**

17 (a) ANNUAL REPORT.—The Board shall, not later
18 than June 30 of each year, submit to Congress an annual
19 report on the operations of the Thrift Savings Plan. Such
20 report shall include, for the prior calendar year, informa-
21 tion on the number of participants as of the last day of
22 such prior calendar year, the median balance in partici-
23 pants’ accounts as of such last day, demographic informa-
24 tion on participants, the percentage allocation of amounts
25 among investment funds or options, the status of the de-

1 velopment and implementation of the self-directed invest-
2 ment window, the diversity demographics of any company,
3 investment adviser, or other entity retained to invest and
4 manage the assets of the Thrift Savings Fund, and such
5 other information as the Board considers appropriate. A
6 copy of each annual report under this subsection shall be
7 made available to the public through an Internet website.

8 (b) REPORTING OF FEES AND OTHER INFORMA-
9 TION.—

10 (1) IN GENERAL.—The Board shall include in
11 the periodic statements provided to participants
12 under section 8439(c) the amount of the investment
13 management fees, administrative expenses, and any
14 other fees or expenses paid with respect to each in-
15 vestment fund and option under the Thrift Savings
16 Plan. Any such statement shall also provide a state-
17 ment notifying participants as to how they may ac-
18 cess the annual report described in subsection (a), as
19 well as any other information concerning the Thrift
20 Savings Plan that might be useful.

21 (2) USE OF ESTIMATES.—For purposes of pro-
22 viding the information required under this sub-
23 section, the Executive Director may provide a rea-
24 sonable and representative estimate of any fees or
25 expenses described in paragraph (1) and shall indi-

1 cate any such estimate as being such an estimate.

2 Any such estimate shall be based on the previous
3 year's experience.

4 (c) DEFINITIONS.—For purposes of this section—

5 (1) the term “Board” has the meaning given
6 such term by 8401(5) of title 5, United States Code;

7 (2) the term “participant” has the meaning
8 given such term by section 8471(3) of title 5, United
9 States Code; and

10 (3) the term “account” means an account es-
11 tablished under section 8439 of title 5, United
12 States Code.

13 **SEC. 406. ACKNOWLEDGEMENT OF RISK.**

14 (a) IN GENERAL.—Section 8439(d) of title 5, United
15 States Code, is amended—

16 (1) by striking the matter after “who elects to
17 invest in” and before “shall sign an acknowledge-
18 ment” and inserting “any investment fund or option
19 under this chapter, other than the Government Se-
20 curities Investment Fund,”; and

21 (2) by striking “either such Fund” and insert-
22 ing “any such fund or option”.

23 (b) COORDINATION WITH PROVISIONS RELATING TO
24 INVESTMENTS IN THE ABSENCE OF AN ELECTION.—Sub-

1 section (d) of section 8439 of title 5, United States Code
2 (as amended by subsection (a)) is further amended—

3 (1) by redesignating subsection (d) as sub-
4 section (d)(1); and

5 (2) by adding at the end the following:

6 “(2)(A) In the case of an investment made under sec-
7 tion 8438(c)(2) in any fund or option to which paragraph
8 (1) would otherwise apply, the participant involved shall,
9 for purposes of this subsection, be deemed—

10 “(i) to have elected to invest in such fund or
11 option; and

12 “(ii) to have executed the acknowledgement re-
13 quired under paragraph (1).

14 “(B)(i) The Executive Director shall prescribe regu-
15 lations under which written notice shall be provided to a
16 participant whenever an investment is made under section
17 8438(c)(2)(B) on behalf of such participant in the absence
18 of an affirmative election described in section 8438(c)(1).

19 “(ii) The regulations shall ensure that any such no-
20 tice shall be provided to the participant within 7 calendar
21 days after the effective date of the default election.

22 “(C) For purposes of this paragraph, the term ‘par-
23 ticipant’ has the meaning given such term by section
24 8471(3).”.

1 (c) COORDINATION WITH PROVISIONS RELATING TO
2 FIDUCIARY RESPONSIBILITIES, LIABILITIES, AND PEN-
3 ALTIES.—Section 8477(e)(1)(C) of title 5, United States
4 Code, is amended—

5 (1) by redesignating subparagraph (C) as sub-
6 paragraph (C)(i); and

7 (2) by adding at the end the following:

8 “(ii) A fiduciary shall not be liable under subpara-
9 graph (A), and no civil action may be brought against a
10 fiduciary—

11 “(I) for providing for the automatic enrollment
12 of a participant in accordance with section
13 8432(b)(2)(A);

14 “(II) for enrolling a participant in a default in-
15 vestment fund in accordance with section
16 8438(c)(2)(B); or

17 “(III) for allowing a participant to invest
18 through the self-directed investment window or for
19 establishing restrictions applicable to participants’
20 ability to invest through the self-directed investment
21 window.”.

22 **SEC. 407. CREDIT FOR UNUSED SICK LEAVE.**

23 (a) IN GENERAL.—Section 8415 of title 5, United
24 States Code, is amended—

1 (1) by redesignating the second subsection (k)
2 and subsection (l) as subsections (l) and (m), respec-
3 tively; and

4 (2) in subsection (l) (as so redesignated by
5 paragraph (1))—

6 (A) by striking “(l) In computing” and in-
7 serting “(l)(1) In computing”; and

8 (B) by adding at the end the following:

9 “(2) Except as provided in paragraph (1), in com-
10 puting an annuity under this subchapter, the total service
11 of an employee who retires on an immediate annuity or
12 who dies leaving a survivor or survivors entitled to annuity
13 includes the days of unused sick leave to his credit under
14 a formal leave system, except that these days will not be
15 counted in determining average pay or annuity eligibility
16 under this subchapter. For purposes of this subsection, in
17 the case of any such employee who is excepted from sub-
18 chapter I of chapter 63 under section 6301(2)(x)-(xiii),
19 the days of unused sick leave to his credit include any un-
20 used sick leave standing to his credit when he was ex-
21 cepted from such subchapter.”.

22 (b) EXCEPTION FROM DEPOSIT REQUIREMENT.—
23 Section 8422(d)(2) of title 5, United States Code, is
24 amended by striking “section 8415(k)” and inserting
25 “paragraph (1) or (2) of section 8415(l)”.

1 (c) EFFECTIVE DATE.—The amendments made by
2 this section shall apply with respect to annuities computed
3 based on separations occurring on or after the date of en-
4 actment of this Act.